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Original Research Article

Gevalin™ *Aegle marmelos* fruit extract improves gastrointestinal symptoms, quality of life and inflammatory markers in symptomatic adults: a randomized, double-blind and placebo-controlled trial

Shankaranarayanan Jeyakodi[1]*, Arunkanth Krishnakumar[1], Mohan Muttanahally Eraiah[2], Jestin V. Thomas[3], M. Mohamed Hussain[4]

[1]Zeus Hygia Lifesciences Pvt. Ltd., Raviraja Industries, TIE, Balanagar, Hyderabad, Telangana, India
[2]Department of General Medicine, BGS Global Institute of Medical Sciences, BGS Health and Education City, Kengeri, Bangalore, Karnataka, India
[3]Department of Clinical Research, Leads Clinical Research and Bio Services Pvt. Ltd., Bangalore, Karnataka, India
[4]Nisa Natural Healing, Dindigul, Tamil Nadu, India

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***Correspondence:**
Shankaranarayanan Jeyakodi,
Email: shankar@zeushygia.com

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ABSTRACT

Background: This is randomised, double-blind, placebo-controlled trial evaluated the efficacy and tolerability of Gevalin™, a standardised *Aegle marmelos* (bael) fruit extract, in adults with chronic upper gastrointestinal symptoms such as postprandial fullness, early satiation, bloating, acidity, and epigastric discomfort etc.
Methods: Eighty-four adults meeting Rome IV criteria were randomised 1:1 to Gevalin™ 250 mg (n=42) or placebo (n=42) once daily for 56 days. The primary endpoint was change in GIS Rating Scale (GSRS) total score from baseline to Day 56. Secondary outcomes were gastrointestinal symptom and Functional Dyspepsia Related Quality of Life (FDQoL) total scores; inflammatory and oxidative stress biomarkers were exploratory. Analysis was per protocol (n=40 vs. 38).
Results: Gevalin™ significantly reduced GSRS total score versus placebo (change -3.87±4.03 vs. -0.55±1.19; difference -3.32, 95% CI -4.66 to -1.98; p<0.0001), a 20.2% vs. 2.7% reduction. Gastrointestinal symptom total score improved significantly (-7.30±5.25 vs. +0.29±2.73; p<0.0001), as did all four FDQoL domains (p≤0.0083). Exploratory analyses showed greater reductions in erythrocyte sedimentation rate (p<0.0001), C-reactive protein (p=0.0119), and 8-hydroxy-2′-deoxyguanosine (p=0.0076), and improved sleep quality (p<0.0001). No serious or treatment-related adverse events (AEs) were reported.
Conclusions: Gevalin™ significantly improved gastrointential symptoms, quality of life, sleep quality, and selected exploratory biomarkers over 56 days, with favorable short-term tolerability, and warrants confirmation in multicentre trials with long-term follow-up.

Keywords: *Aegle marmelos,* Bael, Functional dyspepsia, Nutraceutical, Gut health, Inflammatory biomarkers

INTRODUCTION

Functional gastrointestinal symptoms are highly prevalent worldwide and are associated with substantial impairment in quality of life, daily functioning, and healthcare utilisation.[1] Among adults with chronic upper gastrointestinal symptoms, a substantial proportion fulfil the Rome IV criteria for functional dyspepsia, with global

prevalence estimates of approximately 8-11% when these criteria are applied.[2,3] Rome IV defines functional dyspepsia by the presence of one or more of the following bothersome symptoms: postprandial fullness, early satiation, epigastric pain, or epigastric burning, in the absence of evidence of structural disease that would explain the symptoms.[4] The pathophysiology is multifactorial and includes impaired gastric accommodation, altered duodenal sensitivity, and disturbances in gut–brain signalling,[5] together with low-grade mucosal inflammation and alterations in the upper gastrointestinal microbiome.[6,7]

Current pharmacological approaches, including acid-suppressive agents, prokinetics, and centrally acting neuromodulators, provide incomplete or variable symptom relief in many patients, and concerns regarding tolerability and long-term use remain in some populations.[8] These limitations have increased interest in evidence-based botanical interventions as potential complementary approaches for the management of functional gastrointestinal symptoms. A recently published randomised, double-blind trial comparing the multibotanical formulation Govarcin with metoclopramide in adults with functional dyspepsia-like symptoms reported significant symptomatic improvement with the herbal formulation, further supporting investigation of botanical interventions in this population.[9]

Aegle marmelos (Linn.) *Corréa* (family *Rutaceae*), commonly known as Bael or Bengal quince, has a longstanding history of use in Ayurvedic medicine for gastrointestinal disorders, including diarrhoea, dyspepsia, and gastric ulceration, and is described in the Ayurvedic Pharmacopoeia of India and the AYUSH National Formulary.[10,11] Bael fruit contains several phytoconstituents with reported pharmacological activities, including marmelosin, gallotannic acid, pectins, flavonoids, and alkaloids.[12,13] Preclinical studies have reported antidiarrhoeal activity through inhibition of intestinal hypermotility and secretion,[14] gastroprotective and antiulcer effects in experimental models,[15] inhibition of prostaglandin E_2-mediated gastrointestinal inflammatory responses,[16] and antioxidant/free-radical-scavenging activity associated with marmelosin and phenolic constituents.[17]

Low-grade inflammation and oxidative stress have also been implicated in the pathophysiology of functional GISs, including functional dyspepsia, despite the absence of overt structural mucosal abnormalities.[18] Alterations in inflammatory and oxidative stress markers, including C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), and urinary 8-hydroxy-2′-deoxyguanosine (8-OHdG), have been reported in individuals with functional GISs.[18,19] These observations provide a rationale for evaluating objective inflammatory and oxidative stress biomarkers alongside patient-reported symptom outcomes in clinical studies of botanical interventions.

Gevalin™ is a proprietary, standardized *Aegle marmelos* fruit extract (derived from Bael fruit), manufactured by Zeus Hygia Lifesciences Pvt. Ltd. (Hyderabad, India) and standardized to marmelosin and gallotannic acid. Exact manufacturing parameters, drug-to-extract ratio, batch identification, and quantitative product specifications/results are proprietary and commercially confidential. Each capsule contained 250 mg of Gevalin™ extract; placebo capsules contained microcrystalline cellulose.

Despite the traditional use and preclinical evidence supporting the gastrointestinal effects of *Aegle marmelos*, clinical evidence from well-controlled randomised trials evaluating a standardised *Aegle marmelos* fruit extract in adults with chronic upper GISs remains limited. The present study was therefore designed to evaluate the efficacy and safety of Gevalin™ using contemporary Rome IV diagnostic criteria and validated multidimensional patient-reported outcome measures, including the gastrointestinal symptoms rating scale (GSRS), gastrointestinal symptoms questionnaire, and FDQoL questionnaire, together with objective biomarker assessments.[20-22]

METHODS

Study design and oversight

This was a randomised, double-blind, placebo-controlled, parallel-group clinical trial conducted at BGS Global Institute of Medical Sciences, Bengaluru, Karnataka, India. Ethics committee approval was obtained from the Institutional Ethics Committee of BGS Global Institute of Medical Sciences (EC Registration No: ECR/1307/Inst/KA/2019/RR-24; Approval Reference: BGSGIMS/IEC/App/Apr/2025/003; dated 25 April 2025). The trial was prospectively registered with the Clinical Trials Registry-India (CTRI/2025/05/087128) on 20 May 2025, prior to enrolment of the first participant. The first participant was enrolled on 28 May 2025 and the last participant completed the study on 5 September 2025. The study was conducted in accordance with the Declaration of Helsinki, ICH Good Clinical Practice (GCP) guidelines, and applicable local regulations.

Participants

Eligible participants were male and female adults aged ≥19 years with chronic upper GISs, including one or more of: bothersome postprandial fullness, early satiation, epigastric pain, or epigastric burning. Symptoms were required to be present for the past 3 months, with onset at least 6 months before enrolment, consistent with Rome IV criteria for functional dyspepsia. In addition, participants were required to have a GIS questionnaire total score ≥12 with ≥4 symptomatic items and to provide written informed consent. Rome IV criteria were used to define a homogeneous symptomatic population; the study was conducted and is reported as a trial of a dietary supplement

in symptomatic adults, not as a therapeutic trial in a diagnosed disease.

Exclusion of structural disease

Participants were required to have no evidence of structural disease likely to explain the symptoms. Those with a history of peptic ulcer or reflux oesophagitis within 6 months of the baseline visit, or a history of malignant tumour of the digestive system, were excluded.

Additional exclusion criteria

Exclusion criteria included: severe comorbid cardiovascular, immune, respiratory, hepatobiliary, renal, nervous, musculoskeletal, psychiatric, or infectious disease, or malignancy; prior gastrointestinal surgery (excluding appendectomy and haemorrhoidectomy); use of H_2-receptor antagonists, proton pump inhibitors, anticholinergics, or gastroprotective agents within 2 weeks prior to screening; requirement for continuous corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs), or aspirin >100 mg/day; alcohol use questionnaire score ≥5; uncontrolled hypertension (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg); uncontrolled diabetes (HbA1c >7.0%); serum creatinine >2× upper limit of normal (ULN); aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >3× ULN; known hypersensitivity to any ingredient of the investigational product; pregnancy, lactation, or planned pregnancy; and participation in another interventional clinical trial within 3 months prior to screening.

Investigational product characterization

Gevalin™ is a proprietary, standardized *Aegle marmelos* fruit extract (derived from Bael fruit), manufactured by Zeus Hygia Lifesciences Pvt. Ltd. (Hyderabad, India) and standardized to marmelosin and gallotannic acid.

Each capsule contained 250 mg of Gevalin™ extract; placebo capsules contained 250mg of microcrystalline cellulose.

Randomisation and blinding

Participants were randomised using block randomisation with a 1:1 allocation ratio.

Each eligible participant was assigned a unique randomisation number. Subjects were allocated to one of the two treatment groups (Gevalin™ or placebo) according to the randomisation schedule. Randomised subjects who terminated their study participation for any reason, regardless of whether the investigational product was taken, retained their original randomisation number.

Both the investigator and the participants were blinded to the treatment received. The investigational product was dispensed according to the randomisation code list by an independent dispenser or designated personnel (pharmacist/designee) who did not participate in any other safety or efficacy assessments.

Outcome measures

The primary efficacy endpoint was the change from baseline to day 56 in the GSRS total score, calculated as the sum of the five subscale means (range, 5-35), with higher scores indicating greater symptom burden.[20]

Key secondary efficacy endpoints were the GIS questionnaire total score and FDQoL total score at day 56.[21,22]

GSRS subscale scores, individual item scores, sleep parameters, and inflammatory/oxidative stress biomarkers were evaluated as exploratory outcomes.

The GSRS comprises 15 items across five subscales reflux, abdominal pain, indigestion, diarrhoea, and constipation each rated on a 1-7 Likert scale. The total score is calculated as the sum of the five subscale means (range, 5-35), with higher scores indicating greater symptom burden.[20] The GIS is a 10-item instrument with items scored from 0 to 4, with higher scores indicating greater GIS severity.[21]

The FDQoL is a questionnaire comprising four domains; higher scores indicate greater symptom-related impairment and poorer quality of life, such that reductions from baseline represent improvement.[22] Sleep quality was assessed using a visual analogue scale (VAS; higher scores indicating better sleep quality).

Missing data were not imputed and were not included in the analyses.

Statistical methods

Sample size calculation

A total of 84 subjects (42 per treatment arm) was considered sufficient to detect a clinically important difference between groups with 80% power at a 5% level of significance, assuming a dropout rate of approximately 20%, which was expected to yield at least 67 completers.

Analysis populations

Safety population

All randomised participants who received at least one dose of investigational product (n=42 per group).

Per-protocol (PP) population

Participants who completed the study treatment without any major protocol deviations (Gevalin™: n=40; Placebo:

n=38). The PP population was the primary analysis population for efficacy.

Full analysis set

All randomised participants who received at least one dose of study product and had at least one post-baseline efficacy assessment (n=42 per group).

Statistical tests

Continuous variables were assessed for distributional assumptions using the Shapiro–Wilk test. For the primary efficacy endpoint, the between-group comparison of change from baseline to day 56 in GSRS total score was performed using an independent-samples t test. For secondary and exploratory continuous outcomes, between-group comparisons were performed using the independent-samples t test when parametric assumptions were considered appropriate and the Mann-Whitney U test for non-normally distributed outcomes. Within-group changes were assessed using paired t tests or Wilcoxon signed-rank tests, as appropriate.

No adjustment for covariates was performed. Between-group treatment effects are presented as mean changes from baseline with standard deviations and corresponding p values. Statistical significance was set at the 5% level.

RESULTS

Participant disposition

Participant disposition throughout the study is presented in Figure 1. Ninety-eight individuals were assessed for eligibility, of whom 14 were screen failures. Eighty-four participants were randomised (n=42 per group). Seventy-eight participants completed the study and were included in per-protocol (PP) efficacy population (Gevalin™: n=40; placebo: n=38). Six participants were not included in PP population: one Gevalin™ participant changed location, one was lost to follow-up, one placebo participant was lost to follow-up, and three placebo participants withdrew consent. No participant discontinued because of an AE. Overall retention was 93% (78/84).

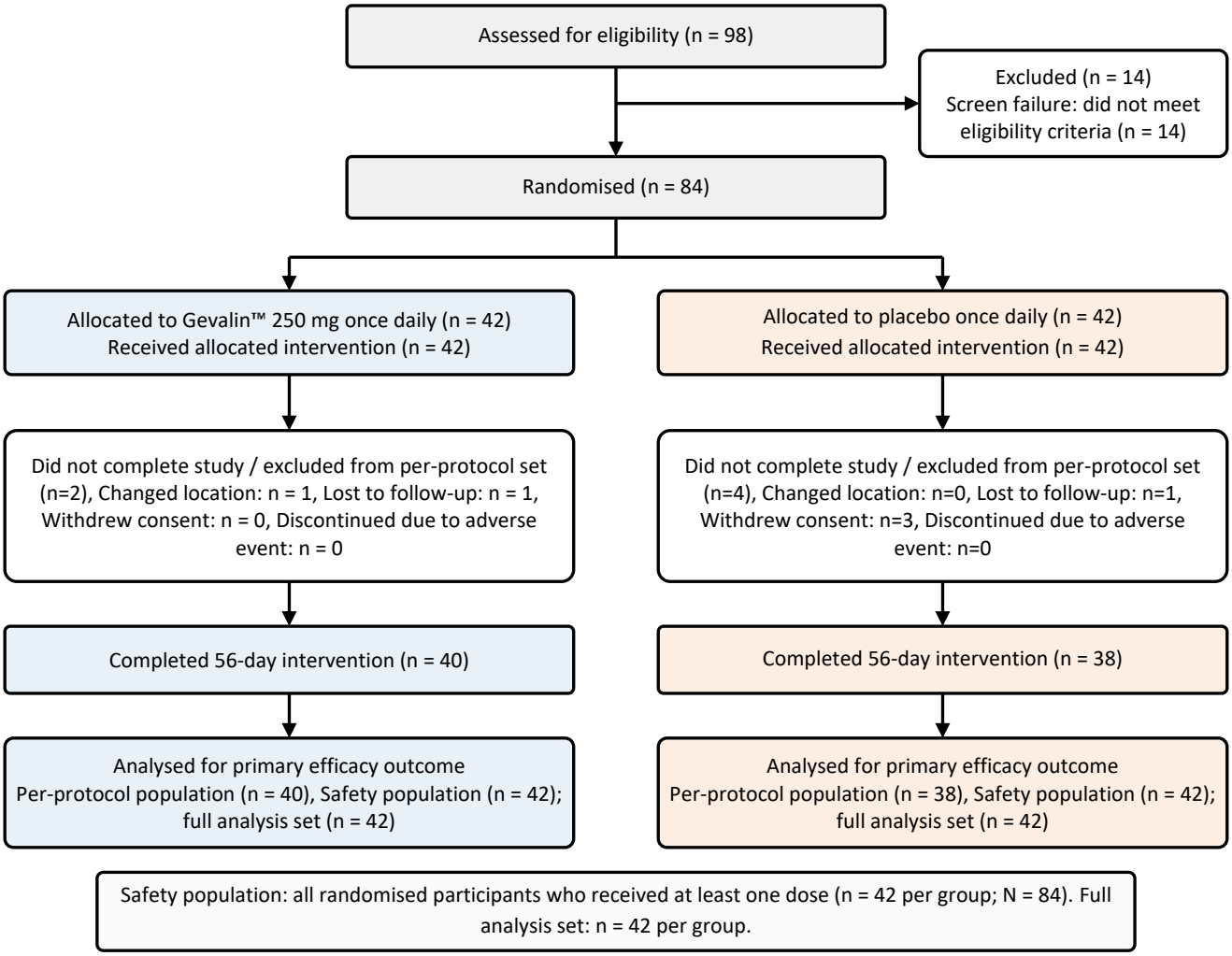


Figure 1: CONSORT flow diagram of participant disposition.

Baseline characteristics

All efficacy analyses were based on change from baseline. The primary between-group comparison for the primary endpoint was performed using an independent samples t test on change scores. Baseline demographic and anthropometric characteristics were comparable between the two groups (safety population, n=84; Gevalin™ vs. placebo: age 44.74±12.22 vs. 43.17±11.19 years, p=0.5405; male sex 21 [50.0%] vs. 23 [54.8%], p=0.6622; BMI 24.89±2.71 vs. 24.18±2.94 kg/m², p=0.2584; independent samples t-test for continuous variables and chi-squared test for categorical variables).

Primary efficacy outcome: GSRS total score

Gevalin™ was associated with a statistically significant reduction in GSRS total score compared with placebo at all post-baseline visits (Table 1, Figure 2A). In the PP population, the mean GSRS total score at day 56 was 15.29±4.17 with Gevalin™ versus 19.65±3.10 with placebo. The mean change from baseline to day 56 was -3.87±4.03 with Gevalin™ versus -0.55±1.19 with placebo (between-group difference in change -3.32 points, 95% CI -4.66 to -1.98; p<0.0001, independent samples t-test), corresponding to a 20.2% reduction from baseline with Gevalin™ versus 2.7% with placebo. Improvements were evident from day 7 and were maintained through day 56.[20]

All five GSRS subscales (reflux, abdominal pain, indigestion, diarrhoea, and constipation) showed significantly greater improvement with Gevalin™ than with placebo at day 56 (Table 1, Figure 2 B). The constipation subscale showed a small, transient worsening at day 7 in the Gevalin™ group, followed by significant improvement by day 56.

GSRS individual item analysis

Significant between-group improvements in change from baseline were observed at day 56 for 13 of 15 GSRS items (Table 2). Items Q6 (rumbling) and Q15 (incomplete evacuation) did not show statistically significant between-group differences at day 56. Constipation-related items (Q10, constipation; Q13, hard stools) showed an initial worsening at day 7 followed by progressive improvement, resulting in a significant net improvement by day 56, consistent with pattern observed for constipation subscale.[20]

Key secondary outcomes: GIS and FDQoL

GIS total score

Gevalin™ was associated with a statistically significant reduction in GIS total score compared with placebo at day 56 (Table 2 and Figure 3). In the PP population, the mean GIS total score at day 56 was 14.83±5.53 with Gevalin™ versus 20.32±4.89 with placebo. The mean change from baseline to day 56 was -7.30±5.25 with Gevalin™ versus +0.29±2.73 with placebo (between-group p<0.0001, independent samples t test). GIS scores improved from day 7 onwards in the Gevalin™ group, whereas placebo scores returned to approximately baseline levels by Day 28 and showed a small non-significant increase by day 56.[21]

GIS individual symptoms

For individual gastrointestinal symptoms, significant between-group differences in change from baseline at day 56 were observed for nausea, sickness, vomiting, abdominal cramps, early satiety, loss of appetite, retrosternal discomfort, and epigastric pain/upper abdominal pain (Table 2). Bloating and acidic eructation/heartburn showed within-Gevalin™ improvement but non-significant between-group differences (p=0.0707 and p=0.1050, respectively).

FDQoL total score and domains

FDQoL total score and all domain scores improved significantly with Gevalin™ compared with placebo at day 56 (Table 3 and Figure 4). Higher FDQoL scores indicate significant impairment; therefore, reductions in score represent improvement in quality of life. The mean change from baseline to day 56 was -9.33±8.87 with Gevalin™versus +1.55±5.77 with placebo (between-group p<0.0001). All four domains eating status, liveliness, psychological status, and role functioning showed statistically significant between-group improvements.[22]

Sleep quality

Sleep quality assessed using a visual analogue scale (VAS; higher=better) and sleep duration was recorded in minutes.

Gevalin™ showed statistically significant improvement in sleep quality VAS score compared with placebo at Day 56 (Table 4 and Figure 5A). The mean change from baseline to day 56 was +0.81±1.31 with Gevalin™ versus -0.36±0.69 with placebo (between-group p<0.0001, Mann–Whitney U test). Sleep duration showed a numerical increase with Gevalin™ (+14.88 minutes) that did not achieve statistical significance versus placebo (between-group p=0.0517).

Exploratory biomarker outcomes

All biomarker analyses are designated exploratory and hypothesis-generating. Table 4 summarises changes from baseline to day 56 for ESR, CRP, IFN-γ, TNF-α, and 8-OHdG (Figure 5 B).

Gevalin™ was associated with a reduction in ESR, whereas the placebo group showed an increase, with a mean change from baseline to Day 56 of −1.35±3.09 mm/h with Gevalin™ versus +1.32±1.91 mm/h with placebo (between-group P<0.0001; Mann–Whitney U test). Similarly, CRP decreased with Gevalin™, whereas the

placebo group showed no meaningful change, with a mean change of −0.29±0.35 mg/l versus +0.01±0.53 mg/l, respectively (between-group P=0.0119). Both groups showed reductions in IFN-γ, with no statistically significant between-group difference in change (P=0.2247). Changes in TNF-α were small and not significantly different between groups (P=0.5647). For 8-OHdG, Gevalin™ showed a small, non-significant reduction, whereas the placebo group showed an increase, with a mean change from baseline to Day 56 of −0.18±0.65 ng/ml versus +0.27±0.77 ng/ml, respectively (between-group P=0.0076). Values are presented as mean ± standard deviation (SD).

Safety

Overall, the safety profile was comparable between the Gevalin™ and placebo groups. Three participants (7.1%) in Gevalin™ group and 5 participants (11.9%) in the placebo group experienced at least one AE. A total of 5 AEs were reported in Gevalin™ group compared with 8 AEs in the placebo group. No serious AEs, treatment-related AEs/AEs leading to discontinuation were reported in either treatment group (Table 5).

At Day 56, the mean change in body weight from baseline was -0.12±0.75 kg in the Gevalin™ group compared with +0.35±0.43 kg in the placebo group. The between-group difference in change from baseline was statistically significant (p=0.0021). Similarly, the mean change in BMI was -0.06±0.29 kg/m² in the Gevalin™ group and +0.13±0.16 kg/m² in the placebo group, with a statistically significant between-group difference (p=0.0007). Laboratory parameters and vital signs remained within normal ranges or showed no clinically significant changes during the study in either treatment group.

AEs

A total of 13 AEs were reported by 8 participants during the study (Gevalin™:5 AEs in 3 participants; Placebo: 8 AEs in 5 participants). All AEs were mild in severity and resolved before the end of study. No SAEs were reported and no participant discontinued due to an AE. The most reported AEs were fever, headache, viral fever, cold, sore throat, gastritis, and upper respiratory tract infection (Table 5). All AEs were assessed as 'not related' to the study product.

Anthropometric measurements

Height remained unchanged in both groups throughout the study. Gevalin™ was associated with a small, decrease in body weight from baseline (64.28±9.42 kg) to the day 56 (63.53±8.98 kg). The placebo group showed a significant increase in weight over the same period, with a mean change from baseline of (63.32±10.54) to Day 56 (63.64±9.89) +0.35±0.43 kg (p<0.0001). The between-group difference in weight change at day 56 was statistically significant, with a mean change of -0.12±0.75 kg in the Gevalin™ group compared with +0.35±0.43 kg in the placebo group (p=0.0021). Similarly, Gevalin™ showed a small, non-significant decrease in BMI from baseline (24.89±2.71 kg/m²) to the day 56 (24.74±2.62 kg/m²). In the placebo group, a non-significant decrease in BMI over time was observed, with a mean change from baseline (24.18 ± 2.94 kg/m^2) to day 56 (24.14±2.94 kg/m^2) of +0.13±0.16 kg/m² (p<0.0001). The between-group difference in BMI change at day 56 was statistically significant, with a mean change of -0.06±0.29 kg/m² in the Gevalin™ group compared with +0.13±0.16 kg/m² in the placebo group (p=0.0007).

Vital signs

Vital signs (temperature, heart rate, systolic and diastolic blood pressure) remained within normal ranges in all participants throughout the study. Some statistically significant between-group differences were observed for temperature and systolic blood pressure at certain visits, but all values were clinically normal and no safety concerns were identified.

Clinical laboratory evaluations

All clinical chemistry (liver function: AST, ALT; renal function: serum creatinine, BUN; fasting blood glucose; lipid profile; TSH; electrolytes; total protein; uric acid) and haematology parameters (haemoglobin, RBC, WBC, platelets, differential counts) remained within normal reference ranges throughout the study. Although small, statistically significant between-group differences were observed for haemoglobin and RBC at baseline and Day 56, all values were within normal limits and no clinically meaningful abnormalities were noted. Urine and stool parameters were also within normal ranges.

Concomitant medications

Overall, 8 participants used at least one concomitant medication during the study (Gevalin™: 3 participants; Placebo: 5 participants). The most used medication was paracetamol. Other concomitant medications included ambroxol + levosalbutamol + guaifenesin, montelukast+fexofenadine, strepsils, domperidone + rabeprazole/pantoprazole, and drotaverine + aceclofenac.

Safety conclusions

Gevalin™ 250 mg once daily was well tolerated over 56 days. No SAEs or discontinuations due to AEs occurred. All AEs were mild, transient, and assessed as unrelated to the study product. Anthropometric, laboratory, and vital sign parameters remained within normal ranges.

The observed between-group differences in weight and BMI were driven by a small increase in the placebo group rather than a decrease with Gevalin™, and together with the absence of treatment-related AEs, are consistent with a favourable short-term tolerability profile for Gevalin™.

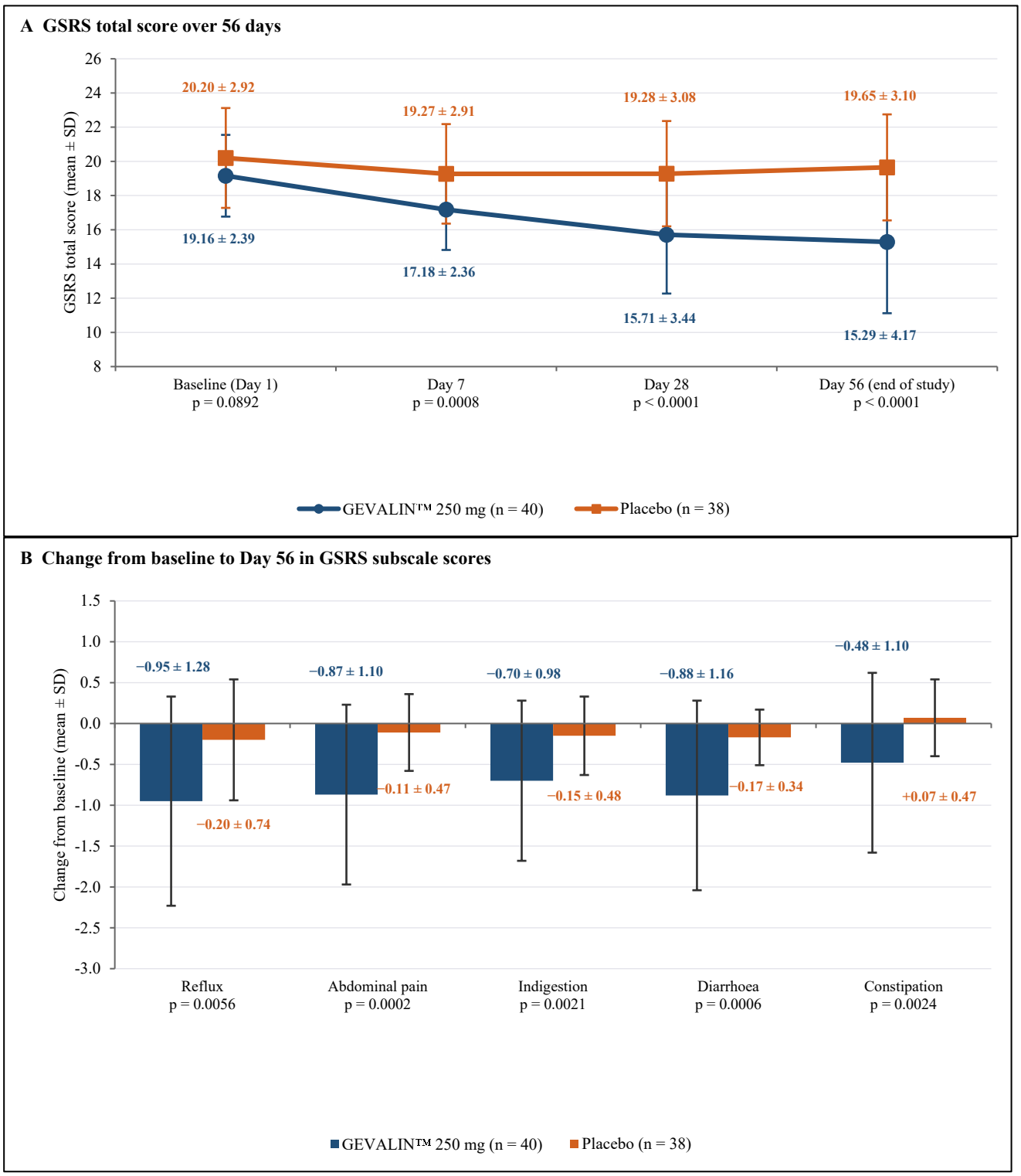


Figure 2: GSRS outcomes (per-protocol population): (A) total score over 56 days, (B) change from baseline to day 56 in subscale scores.

*GSRS outcomes (per-protocol population). (A) GSRS total score across study visits; lower scores indicate lower GIS burden. (B) Change from baseline to day 56 in the five GSRS subscale scores; negative values indicate improvement. Values are mean±SD; error bars represent SD. Between-group p values are shown for each visit (A) and for change from baseline to day 56 (B). GSRS, Gastrointestinal Symptoms Rating Scale; SD, standard deviation.

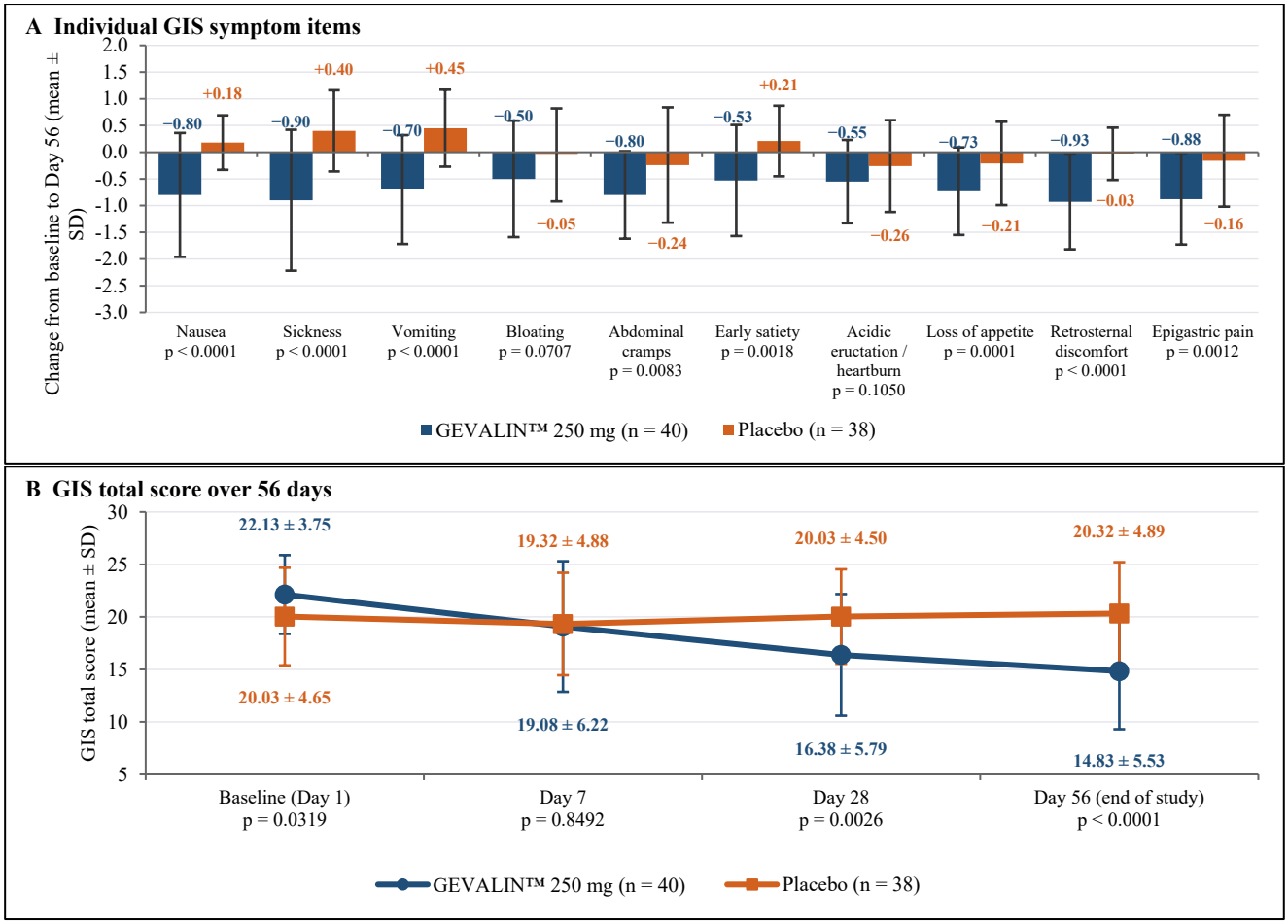


Figure 3: GIS questionnaire outcomes (per-protocol population): (A) individual symptom items, (B) total score over 56 days.

*GIS questionnaire outcomes (per-protocol population). (A) Change from baseline to day 56 in the ten individual GIS symptom items; negative values indicate improvement, and between-group p values are shown beneath each item name. (B) GIS total score across study visits; between-group p values are shown for each visit. Values are mean±SD; error bars represent SD. GIS, Gastrointestinal Symptom; SD, standard deviation.

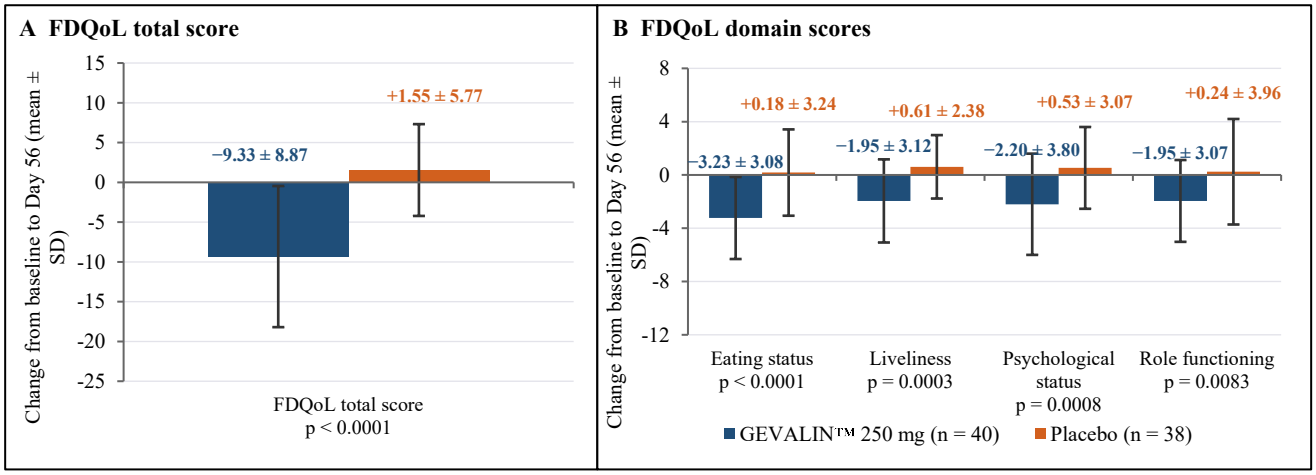


Figure 4: Change from baseline to day 56 in FDQoL scores (per-protocol population): (A) total score, (B) domain scores.

*Change from baseline to day 56 in FDQoL scores (per-protocol population). (A) FDQoL total score. (B) FDQoL domain scores. Lower FDQoL scores indicate better quality of life, so negative values indicate improvement. Values are mean ± SD; error bars represent SD. Between-group p-values, shown beneath the axis labels, compare change from baseline between the Gevalin™ and placebo groups at day 56. FDQoL, Functional Dyspepsia Related Quality of Life; SD, standard deviation.

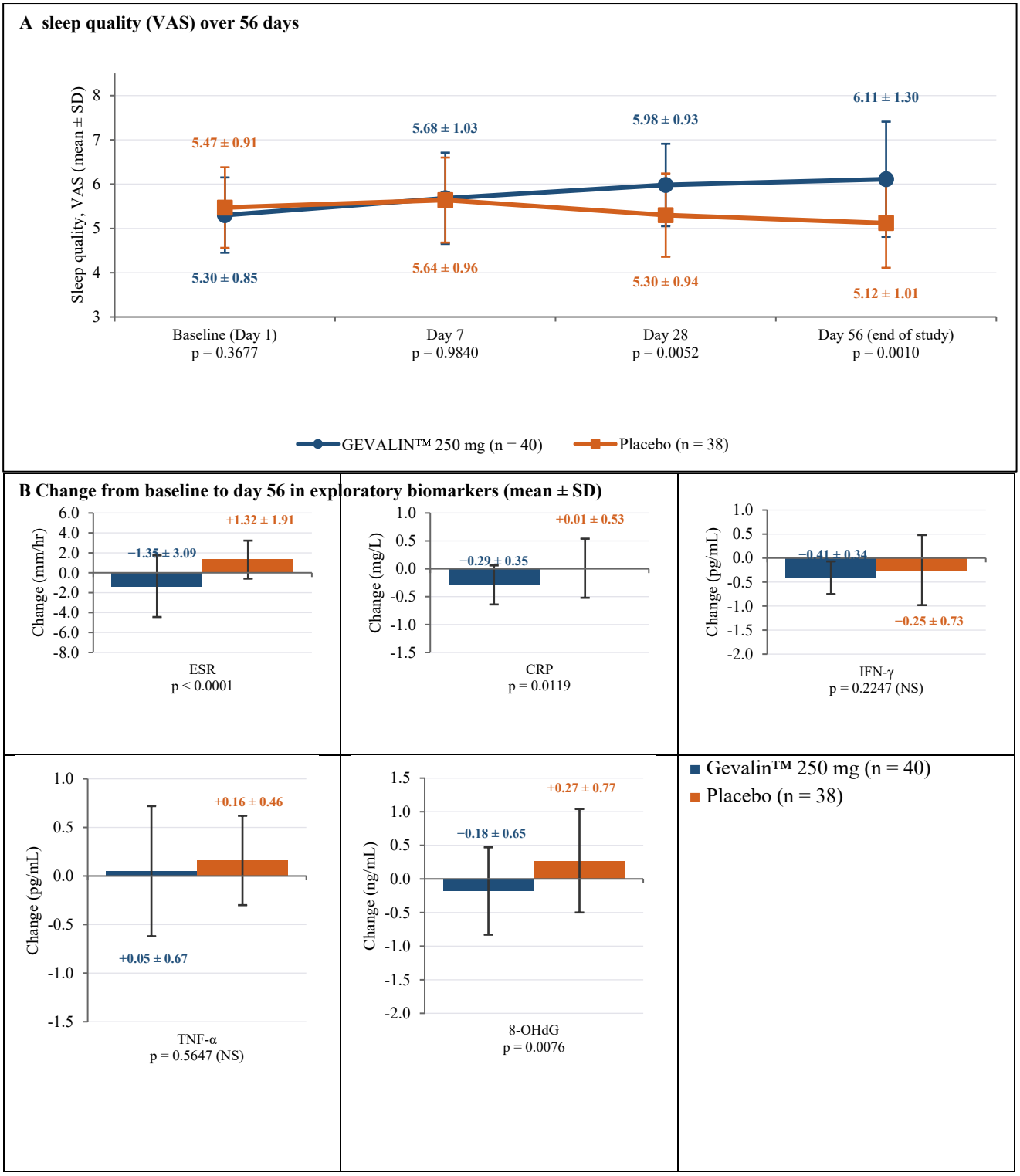


Figure 5: (A) Sleep quality on a visual analogue scale over 56 days and (B) change from baseline to Day 56 in exploratory inflammatory and oxidative stress biomarkers (per-protocol population).

*(A) Sleep quality measured on a visual analogue scale over 56 days; higher scores indicate better sleep quality; between-group p-values are shown for each visit. (B) Change from baseline to Day 56 in exploratory inflammatory and oxidative stress biomarkers; negative values indicate reductions from baseline; between-group p values are shown beneath each biomarker. All biomarker analyses are exploratory and hypothesis-generating. Values are mean±SD; error bars represent SD. NS, not significant; VAS, visual analogue scale; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein; IFN-γ, interferon-gamma; TNF-α, tumour necrosis factor-alpha; 8-OHdG, 8-hydroxy-2′-deoxyguanosine; SD, standard deviation.

Table 1: GSRS total score and subscale scores by treatment group and visit (Per-protocol population).

Outcomes	Timepoint	Gevalin™ (n=40), mean±SD	Placebo (n=38), mean±SD	Between-group p value[a]	Between-group difference in change (95% CI)[b]
GSRS total score (sum of 5 subscale means; range 5-35)	Baseline	19.16±2.39	20.20±2.92	0.0892	-3.32 (-4.66 to -1.98)
	Day 7	17.18±2.36	19.27±2.91	0.0008***	
	Day 28	15.71±3.44	19.28±3.08	<0.0001***	
	Day 56 (EOS)	15.29±4.17	19.65±3.10	<0.0001***	
	Change (Day 56-day 1)	-3.87±4.03 (20.2%)	-0.55±1.19 (2.7%)	<0.0001***	
Reflux subscale	Baseline	3.90±0.73	3.96±0.92	0.9350	
	Day 56	2.95±1.20	3.76±1.11	0.0033**	
	Change	-0.95±1.28	-0.20±0.74	0.0056**	
Abdominal pain subscale	Baseline	3.95±0.72	4.22±0.97	0.1685	
	Day 56	3.08±1.35	4.11±1.03	0.0003***	
	Change	-0.87±1.10	-0.11±0.47	0.0002***	
Indigestion subscale	Baseline	3.90±0.73	4.11±0.88	0.2519	
	Day 56	3.20±1.03	3.97±0.69	0.0002***	
	Change	-0.70±0.98	-0.15±0.48	0.0021**	
Diarrhoea subscale	Baseline	3.83±0.68	4.13±0.68	0.0505	
	Day 56	2.95±1.31	3.97±0.86	0.0001***	
	Change	-0.88±1.16	-0.17±0.34	0.0006***	
Constipation subscale	Baseline	3.58±0.56	3.78±0.73	0.2170	
	Day 56	3.11±0.99	3.85±0.56	0.0005***	
	Change	-0.48±1.10	+0.07±0.47	0.0024**	

*PP, per-protocol; EOS, end of study. [a]Between-group p values for change from baseline based on independent samples t test or Mann-Whitney U test, as appropriate. *p<0.05, **p<0.01, ***p<0.001. [b]Between-group difference in change from baseline with 95% CI, calculated from group means, standard deviations and sample sizes using Welch's method.

Table 2: Item-level scores at baseline and day 56 for the GSRS and GIS (Per-protocol population).

Scales	Item	Gevalin™ baseline, mean±SD	Gevalin™ day 56, mean±SD	Placebo baseline, mean±SD	Placebo day 56, mean±SD	Between-group p value[a]	Between-group difference in change (95% CI)[b]
GSRS	Q1. Upper abdominal pain	3.85±0.98	3.00±1.59	4.16±1.18	4.05±1.29	0.0017**	
	Q2. Heartburn	4.00±0.91	3.03±1.49	3.87±1.04	3.68±1.25	0.0046**	
	Q3. Acid reflux	3.80±0.97	2.88±1.54	4.05±1.11	3.84±1.42	0.0081**	
	Q4. Hunger pains	3.80±0.99	2.90±1.63	4.11±1.62	3.97±1.78	0.0014**	
	Q5. Nausea	4.20±1.07	3.35±1.88	4.40±1.13	4.29±1.21	0.0402*	
	Q6. Rumbling	4.03±1.00	3.55±1.47	4.24±1.67	4.00±1.12	0.5102 (NS)	
	Q7. Bloating	3.93±1.05	3.28±1.01	4.16±1.33	4.00±0.96	0.0221*	
	Q8. Burping	3.90±1.11	3.05±1.45	4.03±1.28	4.03±0.97	0.0021**	
	Q9. Passing gas/flatus	3.75±0.93	2.93±1.37	4.03±1.60	3.84±1.13	0.0093**	
	Q10. Constipation	3.75±1.01	3.15±1.61	3.97±1.20	4.00±0.77	0.0359*	
	Q11. Diarrhoea	3.83±1.01	2.98±1.63	4.08±1.15	3.92±1.40	0.0007***	
	Q12. Loose stools	3.88±0.88	2.85±1.63	4.11±1.37	3.97±1.53	0.0021**	
	Q13. Hard stools	3.63±0.93	2.78±1.59	3.47±1.08	3.74±1.01	0.0001***	
	Q14. Urgency	3.78±1.12	3.03±1.53	4.21±0.91	4.00±1.23	0.0048**	

Continued.

Scales	Item	Gevalin™ baseline, mean±SD	Gevalin™ day 56, mean±SD	Placebo baseline, mean±SD	Placebo day 56, mean±SD	Between-group p value[a]	Between-group difference in change (95% CI)[b]
	Q15. Incomplete evacuation	3.38±1.10	3.40±1.24	3.90±1.27	3.82±0.87	0.9582 (NS)	
GIS	GIS total score (range 0-40; higher=worse)	22.13±3.75	14.83±5.53	20.03±4.65	20.32±4.89	<0.0001***	
	Change from baseline	-	-7.30±5.25	-	+0.29±2.73	<0.0001***	-7.59 (-9.47 to -5.71)
	Nausea	2.48±0.75	1.68±1.21	2.08±0.82	2.26±0.86	<0.0001***	
	Sickness	2.50±0.78	1.60±1.17	1.97±0.82	2.37±0.88	<0.0001***	
	Vomiting	1.48±0.75	0.78±0.97	1.18±0.69	1.63±0.63	<0.0001***	
	Bloating	2.20±0.72	1.70±1.18	2.18±0.69	2.13±1.02	0.0707 (NS)	
	Abdominal cramps	2.20±0.65	1.40±1.01	2.40±0.95	2.16±1.00	0.0083**	
	Early satiety	1.70±2.00	1.18±1.34	1.21±1.82	1.42±1.80	0.0018**	
	Acidic eructation/ heartburn	2.10±0.38	1.55±0.82	2.21±0.94	1.95±0.96	0.1050 (NS)	
	Loss of appetite	3.00±1.75	2.28±1.50	2.84±1.72	2.63±1.92	0.0001***	
	Retrosternal discomfort	2.28±0.60	1.35±0.98	1.79±0.84	1.76±0.88	<0.0001***	
	Epigastric pain/ upper abdominal pain	2.20±0.65	1.33±1.02	2.16±0.89	2.00±0.99	0.0012**	

*PP, per-protocol; GSRS, Gastrointestinal Symptom Rating Scale; GIS, Gastrointestinal Symptom questionnaire; NS, not significant. [a]Between-group p values are for change from baseline (Day 56-day 1) (independent samples t test or Mann-Whitney U test, as appropriate). *p<0.05, **p<0.01, ***p<0.001. [b]Between-group difference in change from baseline with 95% confidence interval, calculated from the group means, standard deviations and sample sizes using Welch's method.

Table 3: FDQoL total score and domain scores at baseline and day 56 (Per-protocol population).

FDQoL domain	Gevalin™ baseline, mean±SD	Gevalin™ day 56, mean±SD	Gevalin™ change, mean±SD	Placebo baseline, mean±SD	Placebo day 56, mean±SD	Placebo change, mean±SD	Between-Group p value[a]	Between-group difference in change (95% CI)[b]
Total score (higher=greater impairment)	50.40±8.50	41.08±7.80	-9.33±8.87	52.21±7.87	53.76±9.58	+1.55±5.77	<0.0001***	-10.88 (-14.25 to -7.51)
Eating status	12.65±2.17	9.43±3.24	-3.23±3.08	12.53±2.47	12.71±3.14	+0.18±3.24	<0.0001***	-3.41 (-4.84 to -1.98)
Liveliness	9.85±2.33	7.90±2.54	-1.95±3.12	10.03±1.78	10.63±2.58	+0.61±2.38	0.0003***	-2.56 (-3.81 to -1.31)
Psychological status	14.08±3.10	11.88±3.03	-2.20±3.80	14.84±2.97	15.37±3.84	+0.53±3.07	0.0008***	-2.73 (-4.28 to -1.18)
Role functioning	13.83±3.15	11.88±3.25	-1.95±3.07	14.82±3.26	15.05±3.80	+0.24±3.96	0.0083**	-2.19 (-3.80 to -0.58)

*PP, per-protocol.[a]Between-group p values are for change from baseline at Day 56 (independent samples t test or Mann-Whitney U test, as appropriate). *p<0.05, **p<0.01, ***p<0.001. [b]Between-group difference in change from baseline with 95% confidence interval, calculated from the group means, standard deviations and sample sizes using Welch's method.

Table 4: Sleep quality, sleep duration and exploratory biomarker outcomes (Per-protocol population).

Parameters	Timepoint	Gevalin™ (n=40), mean±SD	Placebo (n=38), mean±SD	Between-group p value[a]
Sleep quality (VAS)	Baseline	5.30±0.85	5.47±0.91	0.3677
	Day 56	6.11±1.30	5.12±1.01	0.0010
	Change from baseline	+0.81±1.31	−0.36±0.69	<0.0001
Sleep duration (minutes)	Baseline	384.25±57.90	382.11±58.97	0.8718
	Day 56	399.13±61.07	380.00±55.76	0.1524

Continued.

Parameters	Timepoint	Gevalin™ (n=40), mean±SD	Placebo (n=38), mean±SD	Between-group p value[a]
	Change from baseline	+14.88±40.52	-2.11±35.27	0.0517
ESR (mm/hr)	Baseline	18.53±7.11	16.66±7.60	0.2748
	Day 56	17.18±5.77	17.97±7.42	0.6813
	Change from baseline	-1.35±3.09	+1.32±1.91	<0.0001
CRP (mg/l)	Baseline	2.76±1.04	2.62±0.86	0.7641
	Day 56	2.48±0.89	2.62±0.96	0.3704
	Change from baseline	-0.29±0.35	+0.01±0.53	0.0119
IFN-γ (pg/ml)	Baseline	5.74±1.22	5.64±1.07	0.6989
	Day 56	5.33±1.13	5.39±1.10	0.8146
	Change from baseline	-0.41±0.34	-0.25±0.73	0.2247
TNF-α (pg/ml)	Baseline	5.37±1.79	5.30±1.39	0.7225
	Day 56	5.42±1.55	5.45±1.22	0.5788
	Change from baseline	+0.05±0.67	+0.16±0.46	0.5647
8-OHdG (ng/ml)	Baseline	8.57±2.54	8.68±1.99	0.8267
	Day 56	8.39±2.55	8.95±2.18	0.3006
	Change from baseline	-0.18±0.65	+0.27±0.77	0.0076

*PP, per-protocol; VAS, visual analogue scale; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein; IFN-γ, interferon-gamma; TNF-α, tumour necrosis factor-alpha; 8-OHdG, 8-hydroxy-2′-deoxyguanosine. [a]Between-group p-values compare the two groups at each timepoint and for change from baseline (independent samples t-test or Mann–Whitney U test, as appropriate). All biomarker results are exploratory and should be interpreted as hypothesis-generating rather than confirmatory.

Table 5: Safety summary and AEs (Safety population, n=42 per group).

Category	Parameter	Gevalin™ (n=42)	Placebo, (n=42)	Total, (n=84)	Between-group p value
AEs	Participants with ≥1 AE, n (%)	3 (7.1%)	5 (11.9%)	8 (9.5%)	-
	Total AEs reported, n	5	8	13	-
	Serious AEs, n	0	0	0	N/A
	Treatment-related AEs, n	0	0	0	N/A
	AEs leading to discontinuation, n	0	0	0	N/A
	Preferred term: Fever	1	2	3	-
	Preferred term: Cold	1	0	1	-
	Preferred term: Headache	1	2	3	-
	Preferred term: Viral fever	1	1	2	-
	Preferred term: Gastritis	1	0	1	-
	Preferred term: URTI	0	1	1	-
	Preferred term: Sore throat	0	2	2	-
Anthropometric changes	Weight change (kg), day 56 -baseline, mean±SD	-0.12±0.75	+0.35±0.43	-	0.0021**
	BMI change (kg/m²), day 56 - baseline, mean±SD	-0.06±0.29	+0.13±0.16	-	0.0007***
Laboratory and vital signs	Laboratory parameters	All within normal range	All within normal range	-	No clinically significant changes
	Vital signs	All within normal range	All within normal range	-	No clinically significant changes

*AE, adverse event; BMI, body mass index; N/A, not applicable. Data are presented as n (%) for participant-level outcomes and as n for the total number of AE events. Causality was assessed by the investigator. All anthropometric, laboratory, and vital sign values remained within normal physiological ranges throughout the study. *p<0.05, **p<0.01, ***p<0.001

DISCUSSION

This randomised, double-blind, placebo-controlled clinical trial in 84 adults with functional dyspepsia (Rome IV) demonstrates that Gevalin™, a standardised *Aegle marmelos* fruit extract, produces statistically significant improvements in the primary endpoint (GSRS total score), key secondary patient-reported outcomes (Gastrointestinal Symptoms total score and FDQoL), and sleep quality over 56 days.

Gastrointestinal Symptom improvement

The primary finding was a 20.2% reduction in GSRS total score with Gevalin™ versus a 2.7% reduction with placebo (between-group difference in change: -3.32 points; $p<0.0001$), representing a statistically significant improvement in gastrointestinal symptom burden. Improvements were evident from day 7 and were sustained through day 56, suggesting an early onset of symptomatic improvement that was maintained throughout the treatment period. The broad pattern of improvement across multiple gastrointestinal symptom domains, including reflux, abdominal pain, indigestion, diarrhoea, and constipation, with an initial transient worsening of constipation at day 7 that subsequently resolved, is consistent with the reported gastrointestinal activities of bioactive constituents of *Aegle marmelos*.[14-17]

These findings are contextually consistent with other published botanical trials. The Govarcin herbal formulation trial demonstrated significant FD symptom improvement comparable to metoclopramide. Artichoke leaf extract (*Cynara scolymus*) produced clinically meaningful improvements in GISs in a randomized controlled trial in patients with functional dyspepsia.[23] Peppermint/caraway oil combination preparations have similarly demonstrated improvements in multiple GISs in randomized controlled trials of functional dyspepsia.[24,25]

Quality of life

Significant improvements across all FDQoL domains eating status, liveliness, psychological status, and role functioning confirm that the symptomatic benefit of Gevalin™ translated into meaningful functional improvement in this population. The magnitude of FDQoL improvement (mean change: -9.33 points; between-group $p<0.0001$) was substantial and consistent across all domains, suggesting that FDQoL may be a sensitive measure for evaluating treatment-related changes in this population. Similar multi-domain quality-of-life improvements have been reported for effective botanical preparations in FD.

Exploratory biomarker findings

Exploratory biomarker results should be interpreted in the context of both within-group and between-group comparisons (Table 4). Relative to placebo, Gevalin™ was associated with reductions in ESR and CRP. While these findings may suggest an effect on inflammatory status, the exploratory nature of the analyses precludes definitive conclusions regarding an anti-inflammatory effect.

For 8-OHdG, the change from baseline in the Gevalin™ group was not statistically significant. Nevertheless, the between-group comparison was statistically significant, a result that likely reflects both the numerical reduction observed with Gevalin™ and the significant increase observed in the placebo group. This pattern may be consistent with a potential protective effect of Gevalin™ against an increase in oxidative-stress markers; however, this interpretation remains exploratory and should be confirmed in larger studies with prospectively specified biomarker endpoints.

The absence of significant between-group differences in IFN-γ, despite reductions in both groups, and the non-significant numerical trends observed for TNF-α indicate that broad cytokine modulation was not demonstrated in this study. The observed changes in ESR, CRP, and 8-OHdG suggest that the biomarker effects may involve acute-phase inflammatory and oxidative stress pathways. However, these findings are exploratory and do not establish a specific mechanism of action for Gevalin™ at the evaluated dose.

Sleep quality

The significant improvement in sleep quality VAS (+0.81 vs. -0.36; between-group $p<0.0001$) is consistent with the recognised bidirectional relationship between gastrointestinal symptom burden and sleep architecture mediated through gut-brain axis interactions. The absence of a significant between-group difference in sleep duration ($p=0.0517$), despite a trend toward improvement with Gevalin™, suggests that sleep quality rather than duration is the more sensitive parameter in this population and study duration.

Tolerability

The AE profile (Gevalin™: 7.1%; Placebo: 11.9%; no SAEs, no treatment-related AEs, no discontinuations) supports the short-term tolerability of Gevalin™ at 250 mg once daily over 56 days. This 56-day trial was not designed or powered to evaluate long-term safety, cumulative effects, or rare AEs. Findings are interpreted as evidence of favourable short-term tolerability only. Longer-term surveillance studies are required.

Strengths and limitations

Strengths of this study include its randomised, double-blind, placebo-controlled design; high retention (93%); and the use of validated, multidimensional patient-reported outcome measures (GSRS, GIS, FDQoL) alongside exploratory biomarkers.

Limitations include the single-centre design, modest sample size, and 8-week duration, which limit generalisability and preclude assessment of long-term efficacy and safety. No formal adjustment for multiple comparisons was applied; secondary and exploratory outcomes should be interpreted as supportive and hypothesis-generating. The exploratory biomarker analyses were not powered for definitive mechanistic inference and should be interpreted as hypothesis-generating. Future multicentre, longer-duration trials with larger sample sizes and mechanistically-powered biomarker endpoints are warranted to confirm these findings and further elucidate the pharmacological mechanisms of Gevalin™.

CONCLUSION

This randomised, double-blind, placebo-controlled trial demonstrates that Gevalin™, a standardised *Aegle marmelos* fruit extract, significantly improved Gastrointestinal Symptoms Rating Scale (GSRS total score; between-group $p<0.0001$), disease-specific quality of life across all four FDQoL domains, with statistically significant between-group differences, GIS symptom burden (between-group $p<0.0001$), and sleep quality (between-group $p<0.0001$) over 56 days in adults with functional dyspepsia (Rome IV), with a favorable short-term tolerability profile. Exploratory biomarker findings-significant between-group reductions in ESR and CRP, and relative preservation of 8-OHdG versus placebo-are hypothesis-generating and warrant confirmation in adequately powered mechanistic studies; they should not be interpreted as established anti-inflammatory or antioxidant effects of Gevalin™ To our knowledge, these findings represent the first randomised, placebo-controlled evidence for a standardised *Aegle marmelos* extract in symptomatic adults meeting Rome IV criteria for functional dyspepsia. Multicentre replication in diverse populations and long-term follow-up studies are the essential next steps.

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Conflict of interest: Shankaranarayanan Jeyakodi and Arunkanth Krishnakumar are employees of Zeus Hygia Lifesciences Pvt. Ltd., the sponsor and manufacturer of Gevalin™. *The company supported study design, supplied the investigational product and placebo, and contributed to manuscript preparation. Clinical conduct, data collection, and statistical analysis were performed independently by the investigative site and an independent CRO.*
Mohan Muttanahally Eraiah received study funding from Zeus Hygia Lifesciences but has no financial interest in the company. Jestin V. Thomas and M. Mohamed Hussain declare no competing interests
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