

# Mastic Gum as an Adjunct to Antibiotics for *Helicobacter pylori* Eradication: A Randomized Controlled Trial

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## Abstract

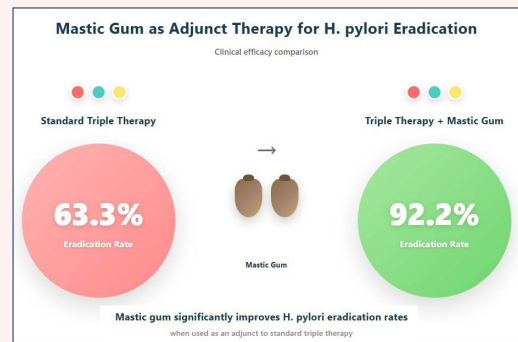
**Background:** *Helicobacter pylori* infection is highly prevalent worldwide and can cause serious complications, necessitating effective eradication regimens. Rising antibiotic resistance has reduced the efficacy of the standard triple therapy involving antibiotics, proton pump inhibitors (PPIs), and bismuth. Mastic gum exhibits promising antibacterial properties and may enhance eradication rates when combined with standard treatment, potentially limiting resistance. This study evaluates a modified triple regimen incorporating mastic gum for *H. pylori* eradication, providing insights into alternative treatment options.

**Methods:** In this randomized controlled trial (Trial Registration: NBEAH-2023-001), 360 *H. pylori*-positive patients were assigned to two groups: Group A received standard triple therapy (clarithromycin, amoxicillin, and omeprazole), and Group B received the same triple therapy plus mastic gum capsules for 10 days. *H. pylori* infection was confirmed pre-treatment by urea breath and fecal antigen tests. Eradication rates post-treatment were compared using chi-square tests, with significance set at  $p \leq 0.05$ . Data analysis was performed using SPSS version 20.

**Results:** In Group B ( $n=180$ ), 14 patients (7.8%) remained *H. pylori*-positive after treatment, yielding a 92.2% eradication rate. In Group A ( $n=180$ ), 66 patients (36.7%) remained positive, yielding a 63.3% eradication rate. The difference in eradication rates was statistically significant ( $P \leq 0.001$ ).

**Conclusion:** Adding mastic gum to standard triple therapy significantly improves *H. pylori* eradication rates. This combination may serve as an effective alternative, particularly in antibiotic-resistant infections, and could help reduce antibiotic use and resistance development.

**Keywords:** Mastic gum, *Helicobacter pylori* infection, Antibiotic resistance, Standard triple-drug, *H. pylori* eradication



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## Introduction

*Helicobacter pylori* infection affects over 50% of the global population and is the primary cause of gastritis, peptic ulcers, and gastric cancer. Standard triple therapy regimens have suboptimal eradication rates due to rising antibiotic resistance, highlighting the need for novel adjuvant treatments to improve outcomes (1). Triple therapy is the standard first-line treatment regimen for *H. pylori* infection. This regimen combines a proton pump

inhibitor (e.g., omeprazole) with two antibiotic agents, typically clarithromycin and amoxicillin. Omeprazole works to decrease stomach acid production, thereby allowing the antibiotics to work more effectively. In addition, clarithromycin and amoxicillin attack *H. pylori* through different mechanisms of inhibiting bacterial protein synthesis. The combination of these three drugs with different mechanisms provides synergistic efficacy in eradicating *H. pylori* infection. The typical dosing of the



triple therapy is omeprazole 20 mg, clarithromycin 500 mg, and amoxicillin 1000 mg, taken together twice daily for 10–14 days. Initially, cure rates with triple therapy exceeded 90%, but eradication rates have declined to 70%–85% in recent years due to increasing antibiotic resistance among *H. pylori* strains. Therefore, modified or alternative regimens are needed to improve efficacy against resistant infections. While once the gold standard treatment, resistance has reduced the effectiveness of the clarithromycin/amoxicillin/omeprazole triple therapy for *H. pylori* eradication (2).

While the triple therapy regimen with a proton pump inhibitor and clarithromycin plus amoxicillin was once the most effective first-line treatment for *H. pylori*, rising antibiotic resistance has become a major challenge, reducing its efficacy. Resistance rates to clarithromycin and metronidazole can exceed 30% in some regions. Similarly, amoxicillin resistance is increasing. This issue has led to suboptimal *H. pylori* cure rates in recent years, often under 80% with standard triple therapy. Other limitations include complex multidrug regimens with frequent dosing, leading to adherence issues, gastrointestinal side effects, and high cost. Additionally, some patients fail to respond even without documented antibiotic resistance. Finally, *H. pylori* reinfection rates after successful eradication are high in certain populations. Overall, these challenges underscore the need for improved first-line treatments that can overcome antibiotic resistance while offering better adherence, tolerability, and eradication durability (3).

Mastic gum (MG) is a resin obtained from the *Pistacia lentiscus* tree native to the Mediterranean region. It has a long history of use in traditional medicine and as a chewing gum. More recently, MG has been studied for its potential health benefits. Research indicates that it may have antibacterial, antioxidant, and anti-inflammatory properties (4). MG contains compounds (e.g., terpenes and masticadienonic acid) that may be biologically active. Potential uses of MG supplements include helping to treat ulcers, reducing dental plaque, and managing cholesterol levels. However, human studies are limited, and more research is still needed to confirm many of the proposed benefits of MG (5).

*H. pylori* is a bacterium that infects the stomach and is a major cause of peptic ulcers, gastritis, and stomach cancer. Eradicating *H. pylori* infection is important for managing these conditions. Research has explored whether MG may help eradicate *H. pylori* due to its antimicrobial properties. Several small clinical studies have reported that MG, in capsule or chewing gum form, shows promise as an adjuvant therapy when combined with antibiotics for *H. pylori* eradication. Although the antibacterial mechanism of MG against *H. pylori* is not entirely clear, it likely relates to its acids and polyphenols that inhibit bacterial growth. MG may also help reduce the side effects of antibiotic therapy (e.g., nausea and diarrhea) in infected patients. However, there is a limited body of

clinical studies, and more research is still necessary. In summary, early evidence indicates MG as a promising supplemental therapy to enhance *H. pylori* eradication when combined with antibiotics, but more robust clinical trials are required to confirm its efficacy (6).

The urea breath test is considered the gold standard noninvasive diagnostic test for *H. pylori* infection. During this test, the patient swallows urea labeled with the carbon isotope (C13). If *H. pylori* is present, the bacteria will metabolize the labeled urea into CO<sub>2</sub> and ammonia, thereby releasing labeled CO<sub>2</sub> that is absorbed into the blood, circulated, and exhaled in the breath, where it can be measured. The urea breath test has high sensitivity and specificity, exceeding 95%, for detecting active *H. pylori* infection. It is simple and quick and requires no endoscopy or tissue samples. The test typically takes 10–30 minutes to complete, and patients receive results the same day. However, its accuracy can be affected by the recent use of antibiotics or medications that suppress gastric acid (7). The urea breath test has some advantages, including its noninvasive nature, speed, and precision. In addition, it is well-tolerated by patients. Moreover, a key benefit is its ability to confirm *H. pylori* eradication after treatment, which is essential for the follow-up (8). Conversely, some limitations are the need for costly labeled urea, the potential for false positives, and the inability to test antibiotic susceptibility. Overall, the urea breath test is considered the best noninvasive option for the diagnosis of active *H. pylori* infection. Its simplicity, accuracy, and rapid results make it a preferred choice for initial diagnosis and confirmation of eradication after antibiotic therapy. More widespread use of the urea breath test can improve the management of *H. pylori* gastritis and related diseases (9).

Likewise, the fecal antigen test is a noninvasive method for detecting active *H. pylori* infection by identifying bacterial antigens in a stool sample. It has high specificity and sensitivity, comparable to the urea breath test. During this test, a small stool sample is collected and analyzed for the presence of *H. pylori* proteins using monoclonal antibodies. The results can be obtained within 1–2 days. The simplicity of collecting stool samples makes this test popular for initial diagnosis and confirmation of eradication after treatment (10). The advantages of the fecal antigen test include its accuracy, low cost, and noninvasive nature requiring only a stool sample. It also has a high negative predictive value, meaning a negative result reliably indicates no infection. However, it may give false positive results in children and cannot assess antibiotic susceptibility (11).

The current research has focused on MG, derived from the *Pistacia lentiscus* tree, which has traditional use against gastrointestinal diseases. MG contains antibacterial, anti-inflammatory, and antioxidant compounds. The study depended on randomized clinical trials to prove that MG may enhance *H. pylori* eradication when added to standard antibiotics.

## Materials and Methods

### Subjects

The study enrolled 360 patients infected with *H. pylori*, diagnosed by urea breath test and fecal antigen test. Patients were randomly allocated to two groups of 180 cases using a computer-generated randomization sequence. Group A received standard triple therapy: clarithromycin 500 mg, amoxicillin 1000 mg, and omeprazole 20 mg twice daily for 10 days. Group B received the same triple therapy, along with one 1000 mg MG capsule, twice daily before meals for 10 days. The MG capsules were standardized products obtained from Jarrow Formulas, Inc. (batch No. 03523mgum120). Demographic data, including age, gender, race/ethnicity, education, marital status, and employment status, were collected using questionnaires. Moreover, clinical data, body mass index (BMI), blood pressure, comorbidities, smoking status, and medications were gathered through physical exams and chart reviews. Ultimately, patient adherence was monitored through pill counts and patient diaries.

### Trial Registration and Ethical Considerations

This randomized controlled trial was registered in the hospital clinical trials registry (trial registration No: NEAH-2023-001). The retrospective analysis covered the period between January 2023 and July 2024. The first participant was enrolled on January 17, 2023. The samples were collected from the patients of the outpatient clinic of the central hospital, Alexandria, and private clinics under the ethical approval of the management of the hospital (approval code: NEAH-EC-2022-085) and the informed consent of the patients.

### Mastic Gum Extraction for Ingestion as Capsules

MG is extracted from the resin of the *Pistacia lentiscus* tree native to Mediterranean regions (12). Trees are tapped for the raw resin, which is collected and cleaned to remove impurities. The resin is then ground into a fine powder to increase the surface area. Next, solvent extraction is used to isolate the bioactive compounds from this powder. Common solvents include ethanol, methanol, acetone, ethyl acetate, and hexane. One method involves dissolving the powder in ethanol, filtering, and evaporating off the ethanol to obtain the purified extract. Further refinement can be performed using liquid-liquid extraction with a water/chloroform mixture to remove additional impurities (13).

The final purified mastic extract is dried completely and milled into a fine, uniform powder optimized for encapsulation. Capsule shells are prepared, typically made from gelatin or cellulose compounds. The mastic powder is loaded into the capsules, often with added fillers (e.g., magnesium stearate) to improve capsule flow properties. Moreover, fill weight and uniformity are verified to meet specifications. Afterward, completed capsules with the extracted MG powder are bottled and packaged for use as a supplement. All manufacturing follows good

manufacturing practices for quality assurance. Typical capsule sizes contain 500–1000 mg of the MG extract (14).

### Statistical Analysis of the Data

The obtained data were fed to the computer and analyzed using the IBM SPSS software package, version 20.0. (Armonk, NY: IBM Corporation). Categorical data were represented as numbers and percentages. The chi-square test was applied to compare the two groups. Furthermore, intention-to-treat and per-protocol analyses were performed, and the significance of the obtained results was measured at the 5% level. The sample size was calculated to achieve 80% power with an alpha of 0.05.

### Results

Table 1 presents the baseline characteristics of the 360 study participants randomized into two groups receiving standard triple therapy (n=180) and triple therapy plus MG (n=180). Based on the statistical analysis, there were no significant differences between the two groups in terms of age, gender, BMI, smoking status, and comorbidities. The average age was around 53 years in both groups, with a roughly even split of males and females. Mean BMI was in the overweight range of 25–26 kg/m<sup>2</sup>. Approximately half of them were never smokers, while 30–31% were current smokers. The prevalence of comorbidities (e.g., hypertension, diabetes, and dyslipidemia) was similar between the groups, affecting 25–40% of participants. In brief, the results demonstrated successful randomization, with the two treatment groups matched for key demographic and clinical characteristics at baseline.

Table 2 compares the incidence of common antibiotic side effects between the two groups during the 10-day treatment period. While diarrhea, abdominal pain, headache, and rash occurred at similar rates in both groups, the addition of MG appeared to reduce the likelihood of nausea. Nearly 30% of patients on standard triple therapy experienced nausea compared to only 21.7% of those also receiving MG ( $P=0.043$ ). This suggests that MG may have some protective benefits in limiting antibiotic-associated nausea when utilized as an adjuvant therapy. Regarding the other side effects (e.g., diarrhea), the MG group showed lower levels, but the differences did not reach statistical significance. Overall, the findings indicated that MG may help decrease nausea from antibiotic triple therapy for *H. pylori* infection.

Table 3 provides the primary outcome data comparing *H. pylori* eradication rates between the two treatment groups at 6–8 weeks post-treatment (extended from the initial 2-week follow-up for more reliable eradication confirmation). It shows the number and percentage of patients who remained positive for *H. pylori* infection after completing their assigned treatment regimen. Patients in group A received standard triple therapy alone, while those in group B received standard triple therapy plus MG supplementation. The results demonstrated a statistically significant difference in treatment failure rates between

**Table 1.** Baseline Characteristics of Study Participants

Characteristic		Triple therapy (n = 180)	Triple therapy with mastic gum (n = 180)	P value
Age (years), mean ± SD		52.3 ± 10.2	53.1 ± 11.3	0.826
Gender, n (%)	Male	90 (50%)	92 (51.1%) 88 (48.9%)	0.654
	Female	90 (50%)		
BMI (kg/m <sup>2</sup> ), mean ± SD		25.7 ± 3.2	26.1 ± 4.1	0.087
Smoking status, n (%)	Current	54 (30%)	57 (31.7%)	0.912
	Former	36 (20%)	39 (21.7%)	
	Never	90 (50%)	84 (46.7%)	
Comorbidities, n (%)	Hypertension	66 (36.7%)	72 (40%)	0.487
	Diabetes	30 (16.7%)	33 (18.3%)	
	Dyslipidemia	45 (25%)	51 (28.3%)	

Note. BMI: Body mass index; SD: Standard deviation.

**Table 2.** Adverse Events During Treatment Period

Adverse event	Triple therapy (n = 180)	Triple therapy + mastic gum (n = 180)	P value
Nausea, n (%)	54 (30%)	39 (21.7%)	0.043
Diarrhea, n (%)	63 (35%)	51 (28.3%)	0.114
Abdominal pain, n (%)	48 (26.7%)	42 (23.3%)	0.315
Headache, n (%)	30 (16.7%)	27 (15%)	0.428
Rash, n (%)	9 (5%)	12 (6.7%)	0.290

the two groups, with group B (MG adjuvant therapy) showing substantially fewer patients remaining positive for *H. pylori* infection compared to group A (standard therapy alone), with a chi-square value of 21.729 and a *P* value of <0.001.

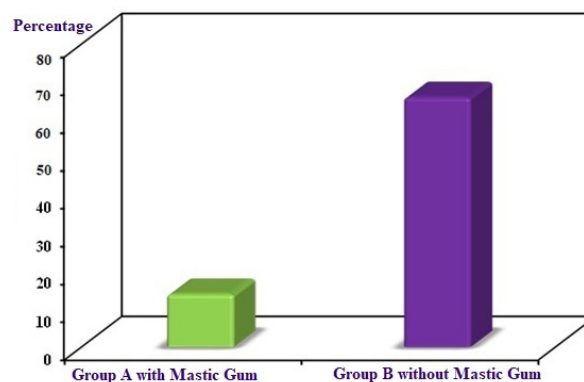
Figure 1 provides a visual representation of the data presented in Table 3, illustrating the comparative eradication success rates between the two study groups. Based on the results, the addition of MG to standard triple therapy (group B) resulted in significantly higher eradication rates compared to standard triple therapy alone (group A). Specifically, group B achieved successful eradication in 166 out of 180 patients (92.2%), while group A achieved successful eradication in only 114 out of 180 patients (63.3%). This represents a clinically meaningful improvement of approximately 29 percentage points in eradication rates when MG is used as an adjuvant therapy.

The results (Table 3 and Figure 1) further revealed that combination therapy with MG was significantly more effective than triple therapy alone. Specifically, only 14 out of 180 patients (7.8%) in group B tested positive after treatment, indicating successful eradication in 166 patients (92.2%) of *H. pylori* infection. This compared to 66 patients still testing positive out of 180 (36.7%), representing successful eradication in only 114 patients (63.3%) in group A, which was significantly lower (*P* < 0.001). Overall, the findings demonstrated that adding MG supplementation to conventional triple therapy markedly improved the eradication rate of *H. pylori* infection compared to triple therapy without MG. The data provide evidence that MG may be a beneficial adjunctive treatment when combined with standard

**Table 3.** Comparison of *H. pylori* Positive Results Between Study Groups at 6-8 Weeks Post-treatment

	Group B (with MG) (n = 180)	Group A (without MG) (n = 180)	χ <sup>2</sup>	P
Positive	14 (7.8%)	66 (36.7%)	21.729	<0.001*

Note. χ<sup>2</sup>: Chi-square test; *H. pylori*: *Helicobacter pylori*; MG: Mastic gum; *P*: *P*-value for comparing between the studied groups; \*Statistically significant at *P* ≤ 0.05.

**Figure 1.** Comparison of *Helicobacter pylori* Eradication Rates Between Study Groups. Note. MG: Mastic gum

antibiotics for treating this bacterial infection.

## Discussion

The expanded randomized controlled trial reinforces the preliminary findings that adding MG supplementation significantly improves *H. pylori* eradication rates compared to standard triple therapy alone. With a sample size of 180 patients per group and an extended follow-up period of 6–8 weeks, the MG adjuvant group demonstrated remarkably higher treatment success of 92.2% versus 63.3% with triple therapy only. The consistency of these results with those of earlier smaller trials provides stronger evidence for the efficacy of MG as an adjuvant therapy to enhance *H. pylori* eradication. The antibacterial properties of MG's bioactive compounds (e.g., terpenes and polyphenols) likely underlie its added benefit. MG appears to synergize with the antibiotics to more potently inhibit *H. pylori* growth and survival.

A major finding of the present study was 92% *H. pylori*

eradication with MG adjuvant versus 63% with standard triple therapy alone over 10 days. In contrast, Paraschos et al reported more modest reductions in *H. pylori* counts with 3 months of mastic extract administration alone without antibiotics (15).

The present study and the study by Dabos et al both evaluated the efficacy of MG supplements for eradicating *H. pylori* infection, using a randomized controlled trial design (16). However, while the findings of the current study revealed the significant benefit of adding MG to standard triple therapy with a 92.2% eradication rate versus 63.3% for triple therapy alone, those of the mentioned study did not demonstrate a considerable difference in eradication rates with 350 mg or 1.05 g per day of MG alone. Dabos et al also assessed combining pantoprazole with MG, which was still ineffective for *H. pylori* eradication. A key difference was the current study's use of MG as an adjuvant to antibiotics, rather than as monotherapy. While Dabos et al concluded that MG has bactericidal effects on *H. pylori*, the current study provided stronger evidence, representing that MG boosts antibiotic efficacy, with eradication rates when combined approaching those of standard therapy before resistance issues emerged (16).

In line with this study, Addissouky et al examined the potential of natural products (e.g., MG) to combat *H. pylori* infection. While they concluded that some in vitro and animal studies support using natural products alone or with triple therapy for *H. pylori*, evidence from human trials was limited (17). In contrast, this randomized controlled trial presented stronger clinical evidence that adding MG to standard antibiotics significantly improves *H. pylori* eradication rates compared to antibiotics alone (92.2% vs. 63.3%).

While the current study and the study by Svingou et al (18) provided useful information on MG, the current study uniquely presented direct clinical evidence, supporting the efficacy of MG against *H. pylori*. The authentication study by Svingou et al aimed to detect MG compounds to confirm sample identity and purity, but did not assess antibacterial effects (18).

The findings of the current study align with the review's discussion of MG clinical trials, showing some evidence that it may reduce *H. pylori* colonization, though efficacy results were inconsistent. While the current study demonstrated a clear benefit of MG for eradication, the review by Abdi et al highlighted the need for larger, high-quality trials to confirm preliminary findings on MG's anti-*H. pylori* effects. Additionally, the review cited uncertainty about whether whole MG versus only certain fractions has activity against *H. pylori*. Conversely, the current study found the whole MG product was effective (19).

The current randomized controlled trial evaluated the effects of MG on *H. pylori* eradication, whereas the MG extract liposome study by Gortzi et al focused on developing a delivery system to improve the bioavailability

and stability of MG's bioactive components (20). The current study tested whole MG capsules as an adjuvant to antibiotics and confirmed significantly improved *H. pylori* cure rates. Contrarily, the liposome study by Gortzi et al encapsulated purified MG extracts in liposomes to enhance their absorption and stability in simulated gastrointestinal conditions. Our findings revealed the therapeutic efficacy of oral MG, and the liposome study by Gortzi et al aimed to optimize MG's delivery using nanotechnology. In summary, the current clinical trial approved the antibacterial effects of MG against *H. pylori*, while the liposome study explored strategies to improve the delivery and stability of MG extracts for potential therapeutic applications (20).

While this study focused specifically on MG, the results highlight the potential for using natural supplementary therapies to enhance *H. pylori* eradication. Other plant-derived compounds (e.g., curcumin, honey, and probiotics) have also exhibited antibacterial activity against *H. pylori* in preliminary studies. Combining traditional medicines with prescription antibiotics may offer improved outcomes versus antibiotics alone. Further research should systematically evaluate different natural adjuvants and their mechanisms of action.

Moreover, other studies should investigate optimal MG dosing, treatment duration, formulations, and mechanisms of action. Comparisons to other adjuvants (e.g., probiotics) would also be useful. Likewise, developing more personalized treatment regimens for *H. pylori* based on pharmacogenomics and strain testing could help overcome antibiotic resistance. Using genomic analysis to predict responses to different antibiotics and tailor regimens accordingly may be one future direction. Similarly, regional surveillance programs tracking local antibiotic resistance patterns can guide empirical treatment choices.

Eradicating *H. pylori* is expected to become increasingly challenging with rising resistance. A multifaceted approach will be required, combining antibiotic stewardship, novel drugs, adjunctive therapies, pharmacogenomics, and personalized medicine. Further research on supplemental therapies (e.g., MG and other natural products) represents an important component of discovering new strategies to improve cure rates while reducing the burden of *H. pylori* infection.

### Study Limitations

Although this randomized trial provided evidence for the use of MG as an *H. pylori* eradication adjuvant, it had several limitations that should be acknowledged. The initial follow-up duration was short at 2 weeks post-treatment, though this was extended to 6–8 weeks for more reliable eradication confirmation. The optimal MG dose and formulation require further study. Mechanistic insights into MG's antibacterial actions are also lacking. Additionally, the cost-effectiveness of adding MG supplementation remains undetermined.

Accordingly, larger multicenter trials of longer duration, pharmacokinetic analyses, head-to-head comparisons with other adjuvants, and economic data would provide more robust support for incorporating MG into routine first-line *H. pylori* therapy. The study also lacked complete blinding, which could potentially introduce bias, although the objective nature of the primary endpoint (bacterial eradication) helps mitigate this concern.

### Conclusion

Overall, it was revealed that adding MG as an adjunctive therapy could significantly improve *H. pylori* eradication when combined with standard antibiotic triple therapy. The MG adjuvant group achieved a 92.2% cure rate versus 63.3% with antibiotics alone over 10 days, with follow-up extended to 6–8 weeks for reliable confirmation. These clinically meaningful results demonstrated MG's efficacy as a natural supplementary treatment to overcome antibiotic resistance and treatment failure.

In summary, MG is a promising, affordable adjunct that synergizes with conventional antibiotics to enhance *H. pylori* eradication. Further large multi-center trials can establish MG supplementation as a first-line regimen component. By incorporating this readily available natural product into clinical practice guidelines, physicians may improve outcomes for millions suffering from this common chronic bacterial infection globally. The current evidence provides the impetus for more research on MG-antibiotic combinations to overcome antibiotic resistance and prevent treatment failures. With further validation, this natural therapy can become an integral part of global *H. pylori* eradication efforts.

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### Clinical Trial Registration

This study was registered as a clinical trial (registration No. NEAH-2023-001).

### Competing Interests

The author hereby declares that they have no competing interests.

### Consent to Participate

Informed consent to participate was obtained from all participants.

### Consent for Publication

Not applicable.

### Data Availability Statement

All data are available, and sharing/publication is possible.

### Ethical Approval

The study was conducted in accordance with the Declaration of Helsinki and received ethical approval from the Ethics Committee (approval code: NEAH-EC-2022-085).

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