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Alginate and lifestyle changes in gastro-oesophageal reflux disease

Submission date
03/06/2025

Recruitment status
Recruiting

Registration date
28/08/2025

Overall study status
Ongoing

Last Edited
09/09/2025

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at how well two treatments work to relieve symptoms of recurring heartburn and indigestion in adults aged 18-70 years. The most prescribed medication for acid reflux is proton pump inhibitors (PPIs). Mostly this is an effective and appropriate treatment in reducing reflux symptoms. However, there is increasing concern around the long-term side effects of these medications. Lifestyle factors such as food choices, obesity, smoking and alcohol can contribute to the severity of acid reflux. This study will assess whether a structured approach to managing these factors alongside the use of Alginate, can be as effective as PPI medication in reducing reflux symptoms.

Who can participate?
Patients aged 18 to 70 years with gastro-oesophageal reflux disease

What does the study involve?
The study will consist of three remote visits and three in-person visits over the 6-month trial period. There will be two groups assigned to two different treatments:
1. Proton Pump Inhibitors (PPIs): PPIs are a medicine that reduce the amount of acid the stomach makes.
2. Alginate combined with dietician advice: Alginates are a group of medicines that counteract (neutralise) the acid in the stomach and form a raft to help prevent the back-flow (reflux) of stomach contents. The dietician will support the participant in making positive lifestyle changes.
The main goal is to see how much the symptoms of heartburn and indigestion improve after 4 weeks of treatment, measured by a symptom questionnaire. Those participants who don't respond to treatment after 4 weeks will receive further investigations. Participants who respond will continue on an appropriate regime and assessed for the next 5 months.

What are the possible benefits and risks of participating?
We hope the trial will be beneficial to participants as we are using treatments known effective in reducing reflux symptoms, as well as participants receiving regular follow-ups with several health care professionals over the 6-month study period. Ultimately, we hope the study can help inform best practice for treating patients presenting with symptoms of gastroesophageal reflux disease.

Risks associated with the study relate to undesirable effects of the treatments provided and to the procedures being performed. The participants will be counselled on all potential risks and they are available to view in the informed consent form.
Collecting blood samples from a vein in your arm can cause temporary discomfort, occasionally bruising/swelling and very rarely an infection at the site of puncture.
Gastroscopy:
1. Sore throat post-procedure is common but mild and resolves quickly.
2. Damage to teeth or bridgework (<1 in 1000)
3. Perforation of the oesophagus, stomach or duodenum (<1 in 10000). This would require urgent hospital admission and may require urgent surgery.
4. Bleeding as a result of the gastroscopy (<1 in 1000). Usually, this can be managed endoscopically but in extreme cases (<1 in 10000) could require surgery.
5. Sedation can result in hypoventilation and hypotension (<1 in 1000 cases)
Oesophageal manometry and 24-hour pH/z monitoring:
1. A sore throat, minor nosebleed and nasal congestion are common (<1 in 10)
2. Oesophageal perforation (<1 in 10000)
3. Aspiration of gastric contents (<1 in 10000)
4. Abnormal heart rhythm (<1 in 10000)
Lactulose hydrogen and methane breath testing:
Occasionally individuals may experience some abdominal bloating and loose stools.
Study procedure related risks will be minimized by only selecting appropriate patients to enter the study with no contraindications to testing. Only accredited units with trained professionals will be permitted to perform procedures.
Undesirable effects relating to omeprazole and alginate, as well as NIMPs are avaliable in the provided SmPCs. Medications will only be prescribed by appropriate professionals.
We do not believe the research will be burdensome to participants, in fact feedback received from the patient advisory group was that the support provided during the study and follow-ups would be an extremely attractive proposition.
The risk of data breach or breach of confidentiality is minimal. The Functional Gut Clinic has SOPs for privacy, confidentiality, data protection and GDPR, as well as annual training. Physical and cyber security protocols are robust and compliant with GCP and cyber secure essentials certification.
All study team members will have up-to-date GCP training.

Where is the study run from?
The Functional Gut Clinic (UK)

When is the study starting and how long is it expected to run for?
May 2025 to August 2026

Who is funding the study?
Reckitt Benckiser Health Limited ("Reckitt")

Who is the main contact?
Dr Sam Treadway, sam.treadway@thefunctionalgutclinic.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
1012284

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
5102101

Study information

Scientific Title
An unblinded, randomised, interventional cohort two-arm trial of alginate with lifestyle interventions versus PPI in the management of mild to moderate gastro-oesophageal reflux

Study objectives
1. To observe the two separate treatment responses of alginate and standard therapy (PPI) in mild to moderate gastro-oesophageal reflux disease.
2. To observe the effects of alginate along with a structured lifestyle intervention and a standard therapy (PPI) in mild to moderate gastro-oesophageal reflux disease.

3. To provide pilot data to inform the design of a large-scale health economics/ non-inferiority study of the intervention.
4. To assess the safety and tolerability of alginate and omeprazole.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/07/2025, West Midlands - Edgbaston Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ , United Kingdom; +44 (0)207 104 8155 ; edgbaston.rec@hra.nhs.uk), ref: 25/WM/0125

Study design
Open randomized controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Gastro-oesophageal reflux disease (GORD)

Interventions
Participants will be randomised into two trial arms:
1. Alginate + lifestyle consultation
2. Omeprazole
A randomisation schedule generated in SAS version 9.4 will be used to randomise subjects.

Trial arm 1:
Alginate + lifestyle consultation: Participants will be given an alginate dose of 20 ml (10 ml of alginate contains sodium alginate 500 mg, sodium bicarbonate 213 mg and calcium carbonate 325 mg per 10 ml) to be taken orally four times a day over the first treatment period (4 weeks), to initiate symptom control. Participants will also be given a GORD lifestyle leaflet at the start of phase 1. The content included in the leaflet is in line with the normal information given to patients as per standard of care in the United Kingdom. Participants will then switch to 10–20 ml to be taken when required up to four times a day for the second treatment period (20 weeks). The purpose of subsequent PRN treatment is to manage symptoms adequately during the structured lifestyle alteration phase.

The lifestyle intervention will consist of two 45-minute diet and lifestyle consultations with a registered dietician. This will consist of motivational interviewing to help enforce the written information provided in the GORD leaflet. The consultation will be a personalised approach to help direct participants where necessary. For some individuals this may include promoting a healthy BMI, advice around alcohol consumption, smoking, portion sizes, carbonated drinks etc. The diet and lifestyle advice will be personalised to the individual and act as a two-way discussion and explore changes to lifestyle and diet and help implement recommendations.

Trial arm 2:
Participants will be given omeprazole 20 mg gastro-resistant capsules to be taken once in the morning, 20 to 30 minutes before food over the first treatment period (4 weeks). Participants will also be given a GORD lifestyle leaflet at the start of phase 1. The content included in the leaflet is in line with the normal information given to patients as per standard of care. After 4 weeks omeprazole will be stopped. During treatment period 2 omeprazole may be re-prescribed for once daily administration if required (upon clinician review). This is in line with the guidance for the treatment of gastro-oesophageal reflux disease. This was chosen as the comparison arm as it replicates the current standard of care when managing immediate symptoms of GORD.

Intervention Type
Drug

Pharmaceutical study type(s)
Therapy

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Omeprazole, alginate

Primary outcome measure
Reflux symptom severity measured using the Heartburn Reflux Dyspepsia Questionnaire (HRDQ) score from baseline to the end of treatment period 1 of the study (4 weeks)

Secondary outcome measures
1. Reflux symptom severity measured using the Heartburn Reflux Dyspepsia Questionnaire (HRDQ) score from baseline to specified timepoints (1 week, 12 weeks, and 24 weeks)
2. Recorded time to onset action, measured by a time to relief question asked at the end of each day in week 1 in the patient diary
3. BMI measured using weighing scales with integrated height ruler from baseline visit (day 0) to end of study (24 weeks)
4. Waist measured using tape measure from baseline visit (day 0) to end of study (24 weeks)
5. Body composition (fat mass %) measured using bioelectric impedance analyser from baseline visit (day 0) to end of study (24 weeks)
6. Cigarette usage (cigarettes/week) measured using unvalidated weekly retrospective lifestyle questionnaire from baseline visit (day 0) to end of study (24 weeks)
7. Alcohol intake (units/week) measured using an unvalidated weekly retrospective lifestyle questionnaire from baseline visit (day 0) to end of study (24 weeks)
8. Blood pressure measured using a sphygmomanometer from baseline visit (day 0) to end of study (24 weeks)
9. Lipid profile determined by assessment of serum cholesterol from baseline visit (day 0) to end

of study (24 weeks)
10. Quality of life measured by GERD Health-Related Quality of Life (GERD-HRQL) score from baseline visit (day 0) to end of study visit (24 weeks)
11. Abdominal symptoms measured by Gastrointestinal Symptom Rating Scale (GSRS) from baseline visit (day 0) to end of study visit (24 weeks)
12. Number of participants in the PPI arm who had to reinitiate PPI therapy, assessed by the reinitiation which will be captured in the eCRF between 5 weeks and 24 weeks
13. Number of PRN doses taken in the second treatment window by the Alginate Arm, measured via patient diary at 5 weeks and 24 weeks
14. The number and type of Adverse Events (AE) reported at any visit either spontaneously by the participant or in response to non-leading questioning; at any time by the patient using the patient diary; at any visit on observation by the Investigator; or at any time by the Investigator in the event of a clinically significant laboratory abnormality

Exploratory outcome measures:
1. Body composition (lean mass %) measured using bioelectric impedance analyser from baseline visit (day 0) to end of study (24 weeks)
2. Body composition (lean mass lbs) measured using bioelectric impedance analyser from baseline visit (day 0) to end of study (24 weeks)
3. Body composition (fat mass lbs) measured using bioelectric impedance analyser from baseline visit (day 0) to end of study (24 weeks)
4. Lipid profile, determined by assessment of LDL from baseline visit (day 0) to end of study (24 weeks)
5. Lipid profile, determined by assessment of HDL from baseline visit (day 0) to end of study (24 weeks)
6. Presence of Small Intestinal Bacterial Overgrowth (SIBO) measured using hydrogen/methane breath test (HMBT) at day 0 and 24 weeks
7. Presence of Intestinal Methanogenic Overgrowth (IMO) measured using hydrogen/methane breath test (HMBT) at day 0 and 24 weeks
8. Total cumulative hydrogen production measured during hydrogen/methane breath test (HMBT) from baseline visit (day 0) to the end of the study (24 weeks)
9. Total cumulative methane production measured during HMBT from baseline visit (day 0) to end of study (24 weeks)
10. Number of non-responders, classified as less than 50% reduction in HRDQ between baseline and 4 weeks
11. Reason for lack of treatment response, identified through non-responder analysis investigations within 28 days of Visit 3 (Week 4)
12. Physical Activity Index level assessed by General Practice Physical Activity Questionnaire (GPPAQ) from baseline visit (day 0) to end of study (24 weeks)

Overall study start date
30/05/2025

Completion date
01/08/2026

Eligibility

Key inclusion criteria
1. Participant has provided written informed consent and is able to comply with all study restrictions

2. Participant is male or female and aged 18 to 70 years old
3. Daily HRDQ score >0.7 on ≥3 days per week, a no greater than moderate score in either heartburn or regurgitation and no more than a mild score in dyspepsia. This will be assessed with a 7-day collection of HRDQ, where participants must complete a minimum of 6 days of data collection.
4. Participants of childbearing potential* must have a negative urine pregnancy test at screening and be willing to use an acceptable method of contraception throughout the study and for one menstrual cycle after last drug administration. In accordance with the Clinical Trial Facilitation Group (CTFG) recommendations, for the purpose of the study the following methods of contraception are acceptable:
4.1. Combined (oestrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal or implantable)
4.2. Progestogen-only oral hormonal contraception (oral, injectable, or implantable)
4.3. Male or female condom with or without spermicide
4.4. Cap, diaphragm or sponge with spermicide
4.5. Intrauterine device (IUD)
4.6. Intrauterine hormone-releasing system (IUS)
4.7. Vasectomised partner (who has received medical assessment of the surgical success)
4.8. Bilateral tubal occlusion
4.9. Sexual abstinence (defined as refraining from heterosexual intercourse during the entire period of risk associated with the study treatments and must be the preferred and usual lifestyle of the participant)

* For the purposes of this study, a participant is considered of childbearing potential, i.e. fertile, following menarche and until becoming post-menopausal unless permanently sterile. (Clinical Trials Facilitation Group, 2020

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Female participant who is pregnant as confirmed by a positive pregnancy test (urine dipstick at screening) or is lactating
2. Participant has a current and previous clinically significant medical history as deemed by the Investigator, including but not limited to cardiovascular, respiratory, gastrointestinal, neurological, metabolic and psychiatric disorders

3. Participant with known Los Angeles (LA) grade C or D oesophagitis, previously demonstrated on endoscopic investigation
4. Participant with a previous or current diagnosis of Barrett's oesophagus
5. Participant with previous evidence of neoplasia on gastroscopy confirmed via histology
6. Participant with red flag symptoms (i.e. dysphagia, unintentional weight loss, anaemia, abdominal mass) unless satisfactorily investigated
7. Participant with renal impairment
8. Participant has previously been prescribed any PPI for more than 14 days historically
9. Participant is currently taking any GLP-1 agonist medication (e.g. semaglutide)
10. Participant has a history of drug or alcohol abuse in the 2 years prior to screening, alcohol use disorders will be screened for using the AUDIT questionnaire
11. Participant has a contraindication to using the investigational products as per the product's SmPC
12. Participant has a known history of previous allergy/sensitivity to PPIs, calcium carbonate, sodium alginate, sodium bicarbonate, substituted benzimidazoles, any of the excipients contained within the investigational medicinal products (alginate and omeprazole) or the non-investigational medicinal product (i.e. lactulose, midazolam, lidocaine, and xylocaine)
13. Participant has received an investigational product or participated in another trial involving a marketed or investigational drug in the 90 days prior to first drug administration
14. Participant has previously been enrolled (randomised) into the current study
15. Participant who is an employee at the site or a partner or first-degree relative of the Investigator
16. Participant fails to satisfy the Investigator of fitness to participate for any other reason

Date of first enrolment
08/09/2025

Date of final enrolment
01/02/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Functional Gut Clinic London
8 Dorset Square
London
United Kingdom
NW1 6PU

Study participating centre
The Functional Gut Clinic Manchester
262 Deansgate

Manchester
United Kingdom
M3 4BG

Sponsor information

Organisation
Reckitt Benckiser Health Limited ("Reckitt")

Sponsor details
Registered Office: 103-105 Bath Road
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clinicalrequests@reckitt.com

Sponsor type
Industry

Website
http://www.rb.com/

Funder(s)

Funder type
Industry

Funder Name
Reckitt Benckiser Health Limited ("Reckitt")

Results and Publications

Publication and dissemination plan
1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation
4. Submission to regulatory authorities

The Sponsor company will provide a Clinical Study Report and/or associated results will be submitted to regulatory authorities where required for the study, for relevant safety updates to regulatory bodies (e.g. DSUR).

The CSR will also be sent to the Investigator. Results from the study will be incorporated into the investigator brochure and will be included in submissions for future studies.

Intention to publish date
01/08/2027

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from PrivacyOffice@reckitt.com

IPD sharing plan summary
Available on request