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Juvia being used for irritable bowel syndrome

Submission date 18/04/2023	**Recruitment status** Stopped	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 10/05/2023	**Overall study status** Stopped	
Last Edited 19/11/2025	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Irritable bowel syndrome (IBS) is a common condition which causes symptoms of abdominal pain, bloating and altered bowel habits. Conventional treatment is frequently unsatisfactory. The study does not involve a medicine. The researchers wish to explore whether giving a food supplement called JUVIA will improve symptoms of IBS. JUVIA is an enzyme-rich malt extract (ERME) that contains a high concentration of enzymes that digest carbohydrates that aim to improve symptoms of IBS. ERME is a by-product of the malting process, in which cereal grains (like barley) are dried. It is sweet and easy to drink and has been used for many years in baking and cookery.

Who can participate?
Patients aged 18 – 65 years with symptoms of IBS

What does the study involve?
The study involves two visits to the research clinic with two telephone calls. Participants provide a urine and stool sample at the start and end of the study. The study duration is 4 weeks and during this time participants take a food supplement (drink i.e. JUVIA) 20 ml twice a day before food.

What are the possible benefits and risks of participating?
Juvia could improve IBS symptoms. There could be slightly looser bowel movements and in the first few days possible worsening of symptoms which should settle quickly.

Where is the study run from?
The Clinical Research Unit, Swansea Bay University Health Board (UK)

When is the study starting and how long is it expected to run for?
October 2022 to October 2024

Who is funding the study?
Ateria Health Ltd (UK)

Who is the main contact?
Kathie Wareham, kathie.wareham@wales.nhs.uk

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
325736

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1168, IRAS 325736, CPMS 55644

Study information

Scientific Title
Pilot study to assess the effect of enzyme-rich malt extract (Juvia) in the treatment of irritable bowel syndrome

Acronym
JUVIA

Study objectives
This study explores whether the administration of a food supplement called JUVIA improves the symptoms of irritable bowel syndrome (IBS). JUVIA is an enzyme-rich malt extract (ERME) that contains a high concentration of enzymes that digest carbohydrates which alters the composition of large bowel contents. ERME is a by-product of the malting process, in which cereal grains (like barley) are dried, and is sweet and easy to drink. It is not classified as a medicine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/04/2023, Wales REC6, c/o Public Health Wales (Building 1, Jobswell Road, St David' s Park, SA31 3HB, UK; +44 (0)1267 611164; Wales.REC6@Wales.nhs.uk), ref: 23/WA/0120

Study design
Open study with a marketed food supplement

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Irritable bowel syndrome (IBS)

Interventions
Participants will be asked to take two tablespoons of JUVIA (enzyme-rich malt extract) each day for 4 weeks and complete a number of questionnaires and provide samples for biochemical analysis.

Intervention Type
Supplement

Primary outcome(s)
IBS severity measured using IBS severity score questionnaire from baseline (visit 1) to 4 weeks (visit 2)

Key secondary outcome(s))
Measured at baseline, 2 and 4 weeks:
1. Severity of abdominal pain measured using IBS patient severity score questionnaire
2. Frequency of abdominal pain measured using IBS patient severity score questionnaire
3. Change in abdominal bloating measured using IBS patient severity score questionnaire
4. Change in bowel habit "satisfaction" measured using IBS patient severity score questionnaire
5. Change in the impact of IBS on lifestyle measured using IBS-OOL questionnaire – validated
6. Change in bowel frequency measured using IBS severity score
7. Change in stool consistency measured using IBS severity score
8. Change in absence from work days related to IBS (as defined by IBS severity score scales) measured using IBS severity score questionnaire
9. Change in IBS quality of life (QoL) questionnaire scores measured using LIFE measures IBS-QOL questionnaire

Safety Endpoints:
The incidence, nature, severity, relatedness, duration, outcome, seriousness and expectedness of treatment-emergent adverse events, measured by patient reporting during the study at any timepoint

Missing Data:
Subjects with missing efficacy data will be analysed on a last-observation-carried-forward basis

Completion date
28/10/2024

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Aged 18-65 years
2. Current symptoms of IBS (abdominal pain and altered bowel habit) ROME IV criteria
3. Prepared to take ERME (JUVIA) for the duration (taste test available for the patient)
4. Normal full blood count within the last 12 months (from medical notes if available)
5. Previous calprotectin (from medical notes if available) <80.ug/g
6. Previous tissue transglutaminase (tTG) (from medical notes if available)
7. Positive for malfermentation as decided by IBS Questionnaire Score
8. Registered with a GP and consent to GP being informed

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
9

Key exclusion criteria
1. Pregnant, planning to become pregnant or lactating
2. Diabetic (or other co-morbidity that the CI considers inappropriate)
3. On a restrictive diet or unwilling or unable to change diet
4. Current medication (e.g. opiates) that may influence bowel symptoms (at the discretion of the CI)
5. Antibiotics in the previous 6 weeks
6. Other gastrointestinal disease (e.g. coeliac, Crohn’s disease or Ulcerative colitis)
7. Significant gastrointestinal surgery (this will be a clinical decision and any patient who has had

a surgical procedure that would change the mechanics of gut function would be excluded)
8. Involved in other gastroenterology research project or other interventional study that would affect results

Date of first enrolment
01/06/2023

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Swansea Bay University Local Health Board
One Talbot Gateway, Seaway Drive
Seaway Parade Industrial Estate
Baglan
Port Talbot
Wales
SA12 7BR

Sponsor information

Organisation
Ateria Health Ltd

Funder(s)

Funder type
Industry

Funder Name
Ateria Health Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results			19/11/2025	No	No
HRA research summary			20/09/2023	No	No
Participant information sheet		02/05/2023	09/05/2023	No	Yes
Protocol file		02/05/2023	09/05/2023	No	No