

# Juvia being used for irritable bowel syndrome

<b>Submission date</b> 18/04/2023	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/05/2023	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/06/2024	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## 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](mailto:kathie.wareham@wales.nhs.uk)

# Contact information

## Type(s)

Principal Investigator

## Contact name

Prof Stephen Bain

## Contact details

Swansea Bay University Health Board

Swansea

United Kingdom

SA2 8PP

+44 (0)1792 530819

s.c.bain@swansea.ac.uk

# Additional identifiers

## EudraCT/CTIS number

Nil known

## IRAS number

325736

## ClinicalTrials.gov number

Nil known

## Secondary identifying numbers

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

**Secondary study design**

Non randomised study

**Study setting(s)**

University/medical school/dental school, Other

**Study type(s)**

Other

**Participant information sheet**

See study outputs table

**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 measure**

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

**Secondary outcome measures**

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

**Overall study start date**

14/10/2022

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

20

**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

United Kingdom

SA12 7BR

## **Sponsor information**

### **Organisation**

Ateria Health Ltd

### **Sponsor details**

21 Albermarle Street

London

England

United Kingdom

W1S 4BS  
+44 (0)1792 530819  
john.hunter@tharos.co.uk

**Sponsor type**  
Industry

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Ateria Health Ltd

## Results and Publications

### Publication and dissemination plan

A final report will be completed and either a full report or summary will be submitted to the REC and R&D after perusal and consent from the Sponsor.

It is intended to publish the results whether positive or negative, in both abstracts and major gastroenterological journals.

**Intention to publish date**  
01/12/2024

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as it is a small pilot study

**IPD sharing plan summary**  
Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		02/05/2023	09/05/2023	No	Yes
<a href="#">Protocol file</a>		02/05/2023	09/05/2023	No	No
<a href="#">HRA research summary</a>			20/09/2023	No	No