

# Effect of enzyme rich malt extract (erme) in treatment of Irritable Bowel Syndrome (IBS)

<b>Submission date</b> 28/11/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/12/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/05/2021	<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 cause of IBS is unknown, but it has been suggested that many of the symptoms result from undigested carbohydrates reaching the large bowel (colon). When this happens the gut bacteria living in the large bowel can ferment undigested food, producing chemicals that cause IBS. These chemicals can be detected in both blood and urine. It has been shown that reducing the number of certain carbohydrates in the diet can improve the symptoms of IBS for some patients. The aim of this study is to find out whether giving a food supplement called enzyme rich malt extract (ERME), which contains a high concentration of enzymes that digest carbohydrates, will improve symptoms of IBS. ERME is a by-product of the malting process, in which cereal grains (like barley) are dried, commonly for making beer. It is sweet, palatable and has been used as an ingredient in baking and cookery for many years.

### Who can participate?

Patients aged 18-65 with IBS

### What does the study involve?

Participants are randomly allocated to take 30 ml of either ERME or an inactive malt product every day for 6 weeks. Participants are followed up by telephone at 2-week intervals until 8 weeks. At week 6 there is a follow-up clinic visit to measure IBS severity using a questionnaire.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

York Teaching Hospital NHS Foundation Trust (UK)

### When is the study starting and how long is it expected to run for?

April 2017 to December 2018

Who is funding the study?  
Arteria Health Ltd

Who is the main contact?  
Tracey Dorey  
tracey.dorey@york.nhs.uk

## Contact information

**Type(s)**  
Public

**Contact name**  
Mrs Tracey Dorey

**Contact details**  
York Teaching Hospital NHS Foundation Trust  
Wigginton Road  
York  
United Kingdom  
YO31 8HE  
+44 (0)1904 726954  
tracey.dorey@york.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
ERMEinIBS

## Study information

**Scientific Title**  
Double blind randomised controlled trial comparing the effect of enzyme rich malt extract with placebo in the treatment of irritable bowel syndrome

**Study objectives**  
There will be a difference in IBS severity score at 6-weeks post randomisation between the two groups.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
North of Scotland Research Ethics Service, 17/08/2017, REC ref: 17/NS/0079

**Study design**

Single-centre double-blind placebo-controlled randomised trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Irritable Bowel Disease

**Interventions**

Participants will be randomised 1:1 to either ERME (enzyme rich malt extract) or control (heat denatured malt product). Participants will be asked to consume 30 ml per day for 6 weeks. Participants will be followed up at 2-week intervals until 8 weeks. At week 6 the follow-up visit will consist of a clinic visit all others will be over the telephone.

**Intervention Type**

Supplement

**Primary outcome measure**

IBS severity is measured using the IBS Severity Score Questionnaire at 6 weeks

**Secondary outcome measures**

1. Severity of abdominal pain is measured using IBS Severity Score Questionnaire at baseline, 2,4, 6 and 8 weeks
2. Frequency of abdominal pain is measured using IBS Severity Score Questionnaire at baseline, 2,4, 6 and 8 weeks
3. Abdominal bloating measured using IBS Severity Score Questionnaire at baseline, 2,4, 6 and 8 weeks
4. Bowel habit "satisfaction" is measured using IBS QoL Questionnaire at baseline 2,4, 6 and 8 weeks
5. impact of IBS upon lifestyle is measured using IBS QoL Questionnaire at baseline, 2,4, 6 and 8 weeks
6. Bowel frequency is measured using self-report by participants at baseline and 6 weeks
7. Stool Consistency is measured using Bristol Stool Chart at baseline and 6 weeks
8. Absence from work days related to IBS is measured using IBS Severity score scales at baseline ,

2,4, 6 and 8 weeks

9. IBS quality of life is measured using IBS QoL Questionnaire Score at baseline , 2,4, 6 and 8 weeks

**Overall study start date**

01/04/2017

**Completion date**

31/12/2018

## **Eligibility**

**Key inclusion criteria**

1. Aged 18-65
2. Current symptoms of IBS (abdominal pain and altered bowel habit) ROME IV
3. Prepared to take ERME for duration (taste test available for patient)
4. Normal full blood count within last 12 months (from notes)
5. Normal calprotectin within last 12 months <50 (from notes)
6. Normal tTG (Tissue Transglutaminase) <10 (from notes)
7. Positive for malfermentation (from IBS Questionnaire Score) – decision by CI
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**

110

**Key exclusion criteria**

1. Pregnant, planning to become pregnant or lactating
2. Diabetic (or other co-morbidity which 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 discretion of the CI)
5. Antibiotics in the previous 6 weeks
6. Other gastrointestinal disease (e.g. coeliac or Crohn's disease)
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**

03/01/2018

**Date of final enrolment**

20/06/2018

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

York Teaching Hospital NHS Foundation Trust

Wigginton Road

York

United Kingdom

YO31 8HE

## **Sponsor information**

**Organisation**

York Teaching Hospital NHS Foundation Trust

**Sponsor details**

Wigginton Road

York

England

United Kingdom

YO31 8HE

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/027e4g787>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Arteria Health Ltd

## Results and Publications

**Publication and dissemination plan**

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

**Intention to publish date**

01/01/2020

**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No