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

Submission date
28/11/2017

Recruitment status
No longer recruiting

Registration date
14/12/2017

Overall study status
Completed

Last Edited
21/05/2021

Condition category
Digestive System

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
HRA research summary			28/06/2023	No	No