Treating people with IBS: a randomised doubleblind placebo controlled trial of IntestAidIB in people with Irritable Bowel Syndrome (IBS)

Submission date	Recruitment status No longer recruiting	Prospectively registered		
13/12/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
15/12/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
22/04/2008	Digestive System			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number N/A

Study information

Scientific Title

Study objectives

H1: treatment with a nucleotide supplement will significantly improve symptoms of irritable bowel syndrome when compared to placebo

H2: psychological measures (depression; anxiety) will predict improvement in symptomatology H3: improvements in symptoms will be accompanied by improvements in psychological state, e. g. anxiety and depression

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the University of East London ethics committee.

Study design

Randomised double-blind placebo-controlled cross-over study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Irritable Bowel Syndrome (IBS)

Interventions

Treatment by nucleotide supplements for 8 weeks and placebo for 8 weeks

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Improvement in daily ratings of seven symptoms of IBS (self report) above placebo level.

Key secondary outcome(s))

Improvement in anxiety and depression ratings (self report) following experimental condition.

Completion date

30/09/2005

Eligibility

Key inclusion criteria

Participants should be aged 1865, should have been diagnosed as having IBS by a qualified medical practitioner, and should have diarrhoea as a main symptom.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Any other co-existing illnesses, and non-confirmation of the diagnosis by GP.

Date of first enrolment

01/10/2004

Date of final enrolment

30/09/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre University of East London

London United Kingdom E15 4LZ

Sponsor information

Organisation

University of East London (UK)

ROR

https://ror.org/057jrqr44

Funder(s)

Funder type

Industry

Funder Name

Wyreside Products Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	08/06/2006		Yes	No