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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure

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

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

Overall study start date
01/10/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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
England

United Kingdom

Study participating centre
University of East London
London
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Sponsor information

Organisation
University of East London (UK)

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Sponsor type
University/education

ROR
https://ror.org/057jrqr44

Funder(s)

Funder type
Industry

Funder Name
Wyreside Products Limited

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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