

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

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|--|---|--|
| Submission date 13/12/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 15/12/2005 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 22/04/2008 | Condition category Digestive System | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Intentional

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 18-65, 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 |