Open label probiotics trial and effects on anxiety/depression in irritable bowel syndrome (IBS) patients

Submission date	Recruitment status	[X] Prospectively registered
15/08/2008	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2008	Completed	Results
Last Edited	Condition category	[] Individual participant data
06/06/2018	Digestive System	Record updated in last year

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

EudraCT/CTIS number 2014-001854-40

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

R16767

Study information

Scientific Title

A pilot study, open label, placebo controlled, non-randomised trial of the influence of Lactobacillus Shirota on anxiety and depression in patients with irritable bowel syndrome (IBS)

Study objectives

Can regular daily consumption of 2 x 65 ml bottles of a probiotic drink (Yakult containing Lactobacillus Shirota) by patients diagnosed with irritable bowel syndrome (IBS) and moderate to severe anxiety and/or depression, have a therapeutic effect on both symptoms of IBS and anxiety/depression in conjunction with routine General Practitioner (GP) care?

Ethics approval required

Old ethics approval format

Ethics approval(s)

REC Yorkshire and The Humber - Sheffield, 16/06/2014, ref: 14/YH/0176

Study design

A pilot study, open label, placebo controlled, non-randomised trial

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Other

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 syndrome, associated anxiety and/or depression

Interventions

Eligible patients will be seen by a therapist trained in the study protocol. Over a 3-month patient recruitment period, 40 patients with a primary diagnosis of IBS will be assessed for IBS symptoms using the ROME II Criteria, anxiety (using the Beck Anxiety Inventory) and depression (using the Beck Depression Inventory II), at baseline and again at the end of a 3-month trial.

During the trial, patients in the trial arm will be provided with routine GP care plus a fortnightly supply of 65 ml bottles of Yakult probiotic drink containing Lactobacillus Shirota sufficient for two bottles per day over the 3-month period. This will be sent direct to either the GP Practice or

the Clinical Research and Trials Unit at UEA, dependent upon the patient's preference, by Yakult for collection by the patient. The control arm will be provided with routine GP care plus a fortnightly supply of a Longlife Milk Shake. If they were taking medication at the beginning of the trial, this would have been at a stable dose for at least 4 weeks before entry into the trial.

Trial and control arm patients will be selected from different GP Practices participating in the trial to minimise cross-over and contamination of information between patients. At the end of the 3-month trial, each patient in both study arms will be asked to complete the outcome measures again and will be asked if they have been given information from any source outside the trial about probiotic supplementation.

Intervention Type

Supplement

Primary outcome measure

- 1. Beck Anxiety Inventory (16+ at baseline to determine moderate to severe anxiety)
- 2. Beck Depression Inventory (20+ at baseline to determine moderate to severe depression)

The outcomes will be taken at baseline and again at 12 weeks. As a pilot study, no interim measures were felt necessary over this relatively short timescale.

Secondary outcome measures

- 1. Irritable bowel syndrome measures using ROME-II Criteria
- 2. Acceptability of intervention (qualitative)

The outcomes will be taken at baseline and again at 12 weeks. As a pilot study, no interim measures were felt necessary over this relatively short timescale.

Overall study start date

06/10/2008

Completion date

03/10/2014

Eligibility

Key inclusion criteria

- 1. Aged between 20 and 50 years, either sex
- 2. Diagnosis of IBS using Rome II Criteria and either moderate/severe anxiety and/or depression
- 3. Medication on stable dosage for at least 4 weeks before entry into the study
- 4. Demonstrates a full understanding of the study protocol and its requirements
- 5. Demonstrates willingness to take either trial probiotic or control placebo as required in the study protocol

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

80 referrals, 40 to final analysis (30 trial arm, 10 control arm)

Key exclusion criteria

- 1. Already taking regular probiotic supplement
- 2. No IBS
- 3. Has IBS but not moderate/severe anxiety or depression
- 4. Unstable medication
- 5. Lactose intolerance
- 6. Demonstrates difficulty in understanding study protocol requirements
- 7. Does not agree to take either trial probiotic or control placebo as required in the study protocol

Date of first enrolment

06/10/2008

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of East Anglia Norwich

United Kingdom NR4 7TJ

Sponsor information

Organisation

Yakult UK Ltd (UK)

Sponsor details

c/o Dr Linda Thomas, UK Science Manager Artemus Odyssey Business Park West End Road Ruislip, Middlesex United Kingdom HA4 6QE

Sponsor type

Industry

ROR

https://ror.org/03wmnrc91

Funder(s)

Funder type

Industry

Funder Name

Yakult UK Ltd (UK) (ref: R16767)

Results and Publications

Publication and dissemination plan

Planned publication in Pharmaceutical Science Journal.

Intention to publish date

03/10/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?HRA research summary28/06/2023NoNo