

Probiotic VSL#3 as a treatment for food intolerant irritable bowel syndrome (IBS)

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 19/07/2017	Condition category Digestive System	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0544129304

Study information

Scientific Title
Probiotic VSL#3 as a treatment for food intolerant irritable bowel syndrome (IBS)

Study objectives

Probiotic VSL#3 as a treatment for food intolerant irritable bowel syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Irritable bowel syndrome (IBS)

Interventions

Patients with suspected food intolerant IBS will be randomised to receive either VSL#3, a probiotic containing 8 non-pathogenic strains of bacteria or a placebo. The dose of either the VSL#3 or the placebo is dependent on the number of daily bowel movements. The patient will be required to take the full dose of VSL#3 or placebo for 6 weeks. A validated symptom score will be used to record symptoms for 2 weeks prior to starting the treatment and for two weeks after one month has elapsed. The validated symptom score will be used to assess if any statistical improvement has occurred in their symptoms. The study will be double-blinded.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

27/03/2006

Eligibility**Key inclusion criteria**

20 subjects aged 18 - 65 years, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

28/03/2003

Date of final enrolment

27/03/2006

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Addenbrooke's NHS Trust

Cambridge

United Kingdom

CB2 2QQ

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Government

Funder Name

Cambridge Consortium - Addenbrooke's (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration