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

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/07/2017	Digestive System	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

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
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 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 measure

Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
28/03/2003

Completion date
27/03/2006

Eligibility

Key inclusion criteria
20 subjects aged 18 - 65 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

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
England

United Kingdom

Study participating centre

Addenbrooke's NHS Trust
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Cambridge Consortium - Addenbrooke's (UK)

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