

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/07/2017	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 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 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