

Does vitamin D alone, or in combination with probiotics improve symptoms of irritable bowel syndrome (IBS) (PROBIVIT)?

Submission date 13/02/2014	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/02/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/01/2016	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Irritable Bowel Syndrome (IBS) is a chronic and debilitating functional disorder of the gastrointestinal tract with serious and detrimental impacts on quality of life. What causes it is largely unknown and there are no effective treatments. This study will investigate whether a vitamin-D deficient subpopulation would respond to supplementation versus either placebo or replete controls, and whether probiotics and vitamin D would have additive benefits. A recent study found that high-dose vitamin D supplementation may lead to remission of symptoms at least in a subset of individuals with IBS. There are no data upon which to base a power calculation and the purpose of this study is to establish such information.

Who can participate?

Subjects with moderate or severe IBS, generally in the Sheffield area of willing to travel to take part.

What does the study involve?

Participants will have an initial screening of symptoms and a blood test to assess vitamin D levels, then they will consume a nasal spray (vitamin D or placebo) and a capsule (probiotics or placebo) for 8 weeks. Participants will report symptom questionnaires across the course of the study and at the end will have a second blood sample measured. Some participants may choose to join a focus group after exit to explore attitudes and outcomes.

What are the possible benefits and risks of participating?

No direct benefits, although participants will be informed of their vitamin D status and will receive advice if this is low. If participants already have high levels of vitamin D, they would risk excess levels and would therefore be excluded from participating.

Where is the study run from?

University of Sheffield (UK).

When is the study starting and how long is it expected to run for?

The study starts in January 2014 and is expected to run for around 8 months, with analysis of data taking sometime longer.

Who is funding the study?

Cultech Ltd.

Who is the main contact?

Dr Bernard Corfe

Contact information

Type(s)

Scientific

Contact name

Dr Bernard Corfe

Contact details

Department of Oncology

University of Sheffield

Beech Hill Road

Sheffield

United Kingdom

S10 2RX

Additional identifiers

Protocol serial number

v2

Study information

Scientific Title

Randomised Controlled Pilot Trial: Does vitamin D alone, or in combination with probiotics improve symptoms of IBS (PROBIVIT)?

Acronym

PROBIVIT

Study objectives

1. Vitamin D supplementation will improve symptoms in irritable bowel syndrome (IBS) patients with a vitamin D deficiency.
2. IBS patients will have low circulating levels of vitamin D and this will be due to either dietary deficiency or malabsorption.
3. Benefits of vitamin D supplementation will be further improved by combination with probiotics.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

2 x 3 fractional factorial design with stratification by vitamin D status

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Irritable Bowel Syndrome

Interventions

After stratification, participants will be randomised into one of three groups:

1. 3000IU vitamin D spray plus placebo for probiotic (maltodextrin)
2. 3000IU vitamin D spray plus Lab4 probiotic (25 billion cfu/capsule)
3. Placebo spray plus placebo for probiotic

Total duration of treatment and follow-up : 8 weeks

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Vitamin D, probiotic

Primary outcome(s)

Reduction in Total Symptom Severity for IBS, measured by VAS at week 8, and a cumulative measure taken fortnightly across the intervention period (weeks 0, 2, 4, 6 + 8)

Key secondary outcome(s)

1. Reduction in composite symptom severity, measured by VAS at week 8, and a cumulative measure taken fortnightly across the intervention period (weeks 0, 2, 4, 6 + 8)
2. Change in vitamin D status, measured in serum at baseline and week 8

Completion date

31/08/2014

Eligibility**Key inclusion criteria**

1. 18-65 years old
2. Diagnosed with IBS
3. Moderate-severe symptom severity

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

All

Key exclusion criteria

1. Any antibiotic use in the past 4 weeks (likely to modify gut flora)
2. Any changes in IBS medication/therapies in the last 4 weeks (may affect IBS symptoms which would influence the results of the trial)
3. Pregnant or lactating females
4. Regular use of vitamin/probiotic supplements (again may influence trial results)
5. Any previous GI surgery, GI cancers or inflammatory bowel disease
6. Diabetes mellitus
7. Current use of antidepressants
8. Current or previous use of antipsychotics

Date of first enrolment

01/01/2014

Date of final enrolment

31/08/2014

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University of Sheffield
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation

University of Sheffield (UK)

ROR

<https://ror.org/05krs5044>

Funder(s)

Funder type

Industry

Funder Name

Cultech Ltd (UK)

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	21/12/2015		Yes	No