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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

Registration date
26/02/2014

Overall study status
Completed

Last Edited
04/01/2016

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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, athough participants will be informed of their vitamin D status and will receive advice is 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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)

Secondary outcome measures
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

Overall study start date
01/01/2014

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
150

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
England

United Kingdom

Study participating centre
University of Sheffield
Sheffield
United Kingdom
S10 2RX

Sponsor information

Organisation
University of Sheffield (UK)

Sponsor details
Western Bank
Sheffield
England
United Kingdom
S10 2TN

Sponsor type
University/education

Website
http://www.shef.ac.uk

ROR
https://ror.org/05krs5044

Funder(s)

Funder type

Industry

Funder Name
Cultech Ltd (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/12/2015		Yes	No