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Can vitamin D improve symptoms and quality of life in people with irritable bowel syndrome (IBS)?

Submission date
23/03/2018

Recruitment status
No longer recruiting

Registration date
25/04/2018

Overall study status
Completed

Last Edited
02/08/2021

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 common condition that affects the digestive system. IBS is usually experienced for a life-time and symptoms include bloating, constipation, diarrhoea, and stomach cramps. These symptoms can affect a person for days, weeks or even months at a time. This can be a difficult condition to live with and can have a large impact on a person's everyday life. The cause of IBS is unknown, although it is thought to be associated with a family history of IBS, stress and certain foods. IBS cannot be cured but can often be managed with medication and dietary changes. Research has shown that people with IBS also have low levels of vitamin D. The aim of this study is to assess whether increasing vitamin D levels in people with IBS helps to improve their symptoms.

Who can participate?
Men and women aged between 18-60 years with a diagnosis of IBS

What does the study involve?
Each person will be put into one of two groups to receive either a vitamin D or placebo (dummy) supplement mouth spray to be taken each day for 12 weeks. All participants will be asked to fill in a total of seven Symptom Severity Questionnaires (SSS-IBS), two Quality of Life Questionnaires (QoL), and one Food Frequency Questionnaire (FFQ). All participants will have blood samples taken at the first and last appointment. This will be done with a finger prick blood test kit. All participants will take a mouth spray, only half of the volunteers will get the active (real) vitamin D supplement.

What are the possible benefits and risks of participating?
The supplement that participants will be taking are well under the advised limit, however, there is a very unlikely risk of vitamin D levels going too high. Side effects of excessive vitamin D levels include raised calcium blood levels, nausea and constipation. Participants will be monitored closely for any problems they may experience during the study. There will also be small risks involved with taking blood samples, such as pain around the site of
insertion, as with any blood test. These risks will be clearly explained to the participants. The

finger prick only occurs twice; at the start and end of the 12 weeks. Volunteers on the active (real) supplement may benefit from their participation in the research as they may see an improvement in their symptoms and all volunteers will receive a £50.00 voucher as a thank you for their participation.

Where is the study run from?
This study will be run from the Medical School at the University of Sheffield.

When is the study starting and how long is it expected to run for?
Recruitment will occur three times over the next 2 years. The first two rounds will occur in the winter periods (Jan-Apr) in 2018 and 2019 in the local area with the goal of reaching 160 volunteers. A further recruitment will take place in 2019 to recruit volunteers from outside the local area and will use postal and online methods to complete the research. The anticipated start date of the trial is September 2018 and will run until September 2020.

Who is funding the study?
This research has been part funded by the University of Sheffield and by an industry partner BetterYou.

Who is the main contact?
The main person to contact regarding this study is Dr Bernard Corfe, Senior Lecturer in Oncology Principal Investigator in Molecular Gastroenterology, Fellow of Insigneo, b.m.corfe@sheffield.ac.uk.

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
016753

Study information

Scientific Title
To assess whether an increase of vitamin D in subjects with irritable bowel syndrome improves symptoms (D-IBS)

Acronym
D-IBS

Study objectives
The hypothesis is that a 3000 IU vitamin D supplement will reduce symptom severity and improve quality of life compared with placebo in participants with IBS, based on self-reported outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Sheffield,19/12/2017, Registration number: 160216727, Reference Number: 016753

Study design
Double-blind placebo-controlled two-arm parallel-design study

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Irritable bowel syndrome

Interventions
Patients administered 3000 IU (75 microg) vitamin D sublingual spray or placebo sublingual spray once daily for 12 weeks

Intervention Type
Supplement

Primary outcome measure
Reduction in Total Symptom Severity for IBS, measured by visual analogue scale (VAS) at baseline and exit, and a cumulative measure taken fortnightly across the intervention period (weeks 0, 2, 4, 6, 8, 10, 12).

Secondary outcome measures
1. Serum vitamin D concentrations will be assessed at baseline and exit: bloodspots will be taken and analysed by liquid chromatography-mass spectrometry .
2. Quality of life is assessed at baseline and exit using The Irritable Bowel Syndrome - Quality of Life questionnaire (IBS-QOL)

Overall study start date
01/09/2017

Completion date
30/09/2020

Eligibility

Key inclusion criteria
Clinical diagnosis of IBS using the ROME criteria and reaching severity score of 150 on SSS scale at time of recruitment. As some participants may have active IBS but historic diagnosis, no one version of ROME is specified as long as a clinical diagnosis was made at the time.

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
160

Total final enrolment
135

Key exclusion criteria
1. Pregnant or lactating
2. Regular use of nutritional supplements
3. BMI >30 kg/m2
4. BMI <18 kg/m2
5. Any history of gastrointestinal disorders (Crohn’s disease, ulcerative colitis, diverticulitis)
6. Diabetes mellitus

Date of first enrolment
08/01/2018

Date of final enrolment
30/07/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The University of Sheffield
The Medical School
Beech Hill Road
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S10 2RX
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Sponsor information

Organisation
The University of Sheffield

Sponsor details
The Medical School
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Sponsor type
University/education

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Not defined

Funder Name
BetterYou

Funder Name
The University of Sheffield

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
As there are no repositories for trial data, we will share an annotated, anonymised spreadsheet on request following publication of any papers.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/07/2021	02/08/2021	Yes	No