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

ISRCTN	ISRCTN75474149
ClinicalTrials.gov identifier	
Public title	Does vitamin D alone, or in combination with probiotics improve symptoms of irritable bowel syndrome (IBS) (PROBIVIT)?
Scientific title	Randomised Controlled Pilot Trial: Does vitamin D alone, or in combination with probiotics improve symptoms of IBS (PROBIVIT)?
Acronym	PROBIVIT
Serial number at source	v2
Study hypothesis	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.
Lay summary	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? 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
Ethics approval	Not provided at time of registration
Study design	2 x 3 fractional factorial design with stratification by vitamin D status
Countries of recruitment	United Kingdom
Disease/condition/study domain	Irritable Bowel Syndrome
Participants - inclusion criteria	1. 18-65 years old 2. Diagnosed with IBS 3. Moderate-severe symptom severity
Participants - 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
Anticipated start date	01/01/2014
Anticipated end date	31/08/2014
Status of trial	Ongoing
Patient information material	Not available in web format, please use the contact details below to request a patient information sheet
Target number of participants	150
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
Primary outcome measure(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).
Secondary outcome measure(s)	1. Reduction in composite symprom 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.

Sources of funding	Cultech Ltd (UK)
Trial website	
Publications	
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