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Effect of the consumption of a fermented dairy product on digestive symptoms and quality of life in patients with irritable bowel syndrome

Submission date 31/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/08/2007	**Overall study status** Completed	
Last Edited 12/09/2013	**Condition category** Digestive System	

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
NU211

Study information

Scientific Title

Study objectives
Irritable Bowel Syndrome (IBS) is a functional bowel disorder in which abdominal pain or discomfort is associated with a change in bowel habit and features of disordered defaecation. IBS is the most common chronic gastrointestinal disorder. The prevalence of IBS in the West Midlands is about 10%, with about half of these patients consulting their General Practitioner (GP) for advice, reassurance or symptom management. IBS is not a life-threatening disease but significantly reduces the quality of life of patients. IBS can have multiple causes and a wide range of symptoms. Symptoms vary greatly between individuals and this makes management of IBS difficult. For the patient, IBS can mean a substantial number of GP visits, prescriptions, tests and days off work, which is important in terms of cost to both the health service and the patient.

Hypothesis:
To determine the effect of consumption of probiotic yoghurt compared with non-probiotic yoghurt on symptoms of IBS and quality of life in patients with constipation predominant IBS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Nottingham Local Research Ethics Committee 2 on the 26th January 2007 (ref: 06/Q2404/172).

Study design
A multicentre, double blind randomised controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Irritable Bowel Syndrome (IBS)

Interventions

1. Intervention group: receive two daily servings of a probiotic yoghurt which contains live strains of bacteria
2. Control group: receive two daily servings of a yoghurt that does not contain probiotic bacteria

The total duration of the study is 14 weeks, which includes two weeks of completing a daily diary only, followed by 12 weeks of eating two yoghurts daily and completing a daily diary. Participants will meet with a researcher on four occasions.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Probiotic yoghurt

Primary outcome measure
The primary outcome measure is the effect on Subjects' Global Assessment (SGA) of IBS symptoms relief at four weeks

Secondary outcome measures
1. Effect on SGA of IBS symptoms relief over 12 weeks and per week
2. Effect on bloating, abdominal pain and flatulence/passage of gas over 4 and 12 weeks and per week
3. Effect on composite score of IBS symptoms (sum of severity score of bloating, abdominal pain and flatulence/passage of gas) over 4 and 12 weeks and per week
4. Effect on bowel function (stool frequency and consistency, bowel movement difficulty) over 4 and 12 weeks and per week
5. Effect on quality of life (IBS-QOL) after 4, 8 and 12 weeks
6. Effect on severity of IBS (IBS-SSS) after 4, 8 and 12 weeks
7. Effect on IBS specific symptoms questionnaire (pain, constipation and diarrhoea) after 4, 8 and 12 weeks
8. Effect on responders rate for SGA of IBS symptoms relief over 1 - 4 weeks and 1 - 12 weeks period (a responder will be defined as a patient who reported satisfactory relief on at least 50% of weeks of the considered period)
9. Effect on responders rate for bloating severity at 4 weeks and 12 weeks (a responder will be defined as a patient who reported at least a 50% decrease of bloating severity at 4 or 12 weeks)

Overall study start date
01/01/2007

Completion date
30/11/2007

Eligibility

Key inclusion criteria
1. Female or male free-living patients aged from 18 to 65 years
2. Patient with a diagnosis of IBS according to Rome III criteria: recurrent abdominal pain or

discomfort at least three days per month in the last three months associated with two or more of the following:
2.1. Improvement with defaecation
2.2. Onset associated with a change in frequency of stool
2.3. Onset associated with a change in form (appearance) of stool
3. Patient with a diagnosis of IBS according to Rome III criteria with symptom onset at least six months prior to diagnosis
4. Patient with constipation-predominant symptom profile according to Rome III criteria: hard or lumpy stools (type 1 - 2 of Bristol scale) greater than 25% and loose (mushy) or watery stools (type 6 - 7 of Bristol scale) less than 25% of bowel movement
5. Patient having an Irritable Bowel Syndrome Severity Scoring System (IBS-SSS) score greater than 75
6. Patient passing three or less stools per day during baseline data gathering phase

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Patient with a diagnosis of IBS with diarrhoea-predominant, mixed and unsubtyped according to Rome III criteria: loose (mushy) or watery-type 6-7 of Bristol scale) stools greater than 25% and hard or lumpy (type 1-2 of Bristol scale) stools less than 25% of bowel movement
2. Patient with a diagnosis of IBS with clinical signs of alarm (rectorragy, fever, associated inflammatory articular signs, recent weight loss)
3. Commencement of an anti-psychotic medication within the prior month
4. Change of prescribing for IBS-symptoms within the prior month
5. Change of dietary habit within the preceding month
6. Patient with known organic disease, including an inflammatory bowel disease, a benign or malign tumour of intestine or colon and significant systemic disease
7. Patient undergoing general anaesthesia in the month prior to inclusion
8. For female patient:
8.1. Pregnant patient or patient planning to become pregnant during the study
8.2. Breast-feeding
9. Patient currently involved in any other clinical trial or having participated in a trial for IBS within the preceding three months
10. Patient with known lactose intolerance or immunodeficiency
11. Patient with known allergy to product component (milk protein for example)
12. Patients who are morbidly obese (Body Mass Index [BMI] greater than 35) or where BMI is less than 18 (as this will be deemed suggestive of abnormal diet or function)
13. Patients with history of laxative abuse

Date of first enrolment
01/01/2007

Date of final enrolment
30/11/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Care and General Practice
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Sponsor information

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Sponsor type
Industry

Website
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Funder(s)

Funder type

Industry

Funder Name
Groupe Danone (France)

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	07/03/2013		Yes	No