ISRCTN41607808 https://doi.org/10.1186/ISRCTN41607808

Effect of a probiotic blend on bloating and colonic transit time in participants with self-reported bloating and constipation

Submission date
25/09/2015

Recruitment status
No longer recruiting

Registration date
02/10/2015

Overall study status
Completed

Last Edited
29/05/2019

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Constipation is when a person is not passing stools regularly, or cannot completely empty their bowels. Women and the elderly are especially at increased risk for constipation. Constipation results in lower quality of life and significant healthcare costs. Bloating, a feeling of increased pressure within the abdomen, is a bothersome symptom that affects a third of the general population and almost all irritable bowel syndrome (IBS) patients. This study assesses the effect of a probiotic blend in people with bloating and constipation.

Who can participate?
People aged 18 - 70 with bloating and constipation

What does the study involve?
Participants are randomly allocated to take either a probiotic blend or placebo (dummy) capsule for 14 consecutive days. During the study, participants should avoid taking other probiotics or probiotic-containing products, prebiotics and nutritional supplements (vitamins or minerals such as calcium, magnesium or iron). They should also avoid making any significant changes to their diet and physical exercise habits during the study. Participants attend the clinic for five visits over a period of 4 weeks. Participants' Colon Transit Time is measured at the start and end of the study. This is a measure of the time it takes for a meal to travel through your digestive system. Measuring Colon Transit Time requires that participants swallow something that can be tracked or traced as it travels through your digestive system. For this study, participants have to swallow a capsule containing small indigestible pellets, for six consecutive days. After the six days participants have an x-ray to show how the pellets have moved through their intestines. In addition, a stool sample is collected at home in advance of the day 0 and day 14 visits.

What are the possible benefits and risks of participating?
The probiotic may help to improve symptoms of bloating and constipation but there is no guarantee that being in this study will help. Information from this study might help researchers to improve the treatment of patients with constipation. The five strains in the probiotic have been tested previously and have been shown to be effective with no serious side effects. There

are no allergens present in the probiotic blend or the capsules, so there should be no risk of an allergic reaction to these. There is a risk of an allergic reaction to the small indigestible pellets. For this reason, participants with allergies to barium sulfate or additives in polyurethane are excluded from the study as these conditions increase the risk of allergic reactions.

Where is the study run from?
Atlantia Food Trials (Ireland)

When is the study starting and how long is it expected to run for?
August 2015 to February 2016

Who is funding the study?
Danisco Sweeteners Oy (Finland)

Who is the main contact?
Mary Osborne
mosborne@atlantiafoodtrials.com

Contact information

Type(s)
Public

Contact name
Ms Mary Osborne

Contact details
Atlantia Food Clinical Trials
Bridge House, Unit 2
Skehard Road
Blackrock
Cork
Ireland
T12 H2TK
+353 (0)21 423 1000
mosborne@atlantiafoodtrials.com

Type(s)
Scientific

Contact name
Ms Andrea Doolan

Contact details
Atlantia Food Clinical Trials
Bridge House, Unit 2
Skehard Road
Blackrock
Cork
Ireland
T12 H2TK

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
AFCRO-056

Study information

Scientific Title
Effect of a probiotic blend on bloating and colonic transit time in participants with self-reported bloating and constipation: a double-blind, randomized, placebo-controlled trial

Study objectives
To determine the effect of a 14-day supplementation of a probiotic blend on abdominal bloating in a generally healthy adult population suffering from bloating and constipation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College Cork, Clinical Research Ethics Committee, 18/08/2015, EC Ref ECM 4 (k) 11/08 /15

Study design
Randomized double-blinded placebo-controlled multicenter study with two arms and parallel groups

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Abdominal bloating

Interventions
The investigational product (IP) is a mixture of five live freeze-dried Lactobacillus & Bifidobacterium strains. Microcrystalline cellulose (MCC) is added to the active blend as an inert carrier, and it functions as placebo as well. Neither IP contains any other active ingredients than the these bacterial strains. All of the probiotic strains included in the IP are manufactured by Danisco USA Inc. in accordance with U.S. Food & Drug Administration's (FDA) regulations. All species included in the IP are considered safe for human consumption.

Participants are randomized to take either the probiotic blend or placebo administered in capsules (1 capsule daily) for 14 days. There is no follow-up of the treatment arms.

Intervention Type
Supplement

Primary outcome measure
The primary objective of the present clinical trial is to independently assess the effect of orally administered 2-week supplementation of a probiotic blend (or placebo) on bloating in general adult population with self-reported bloating and constipation. The probiotic blend (or placebo) will be administered in capsules (1 capsule daily) for 14 days (for strain-wise dosages in a capsule, see Table 1). The bloating severity and the number of days with bloating will be determined for 14 days with a daily eDiary using visual analogue scale (VAS). The primary endpoint will be a composite score of percentage of days with bloating times the average severity of the VAS, frequency*severity.

Secondary outcome measures
The secondary objectives of this clinical trial are to assess the effect of 2-week supplementation of a probiotic blend (or placebo) on the following parameters in adults with self-reported bloating and constipation:
1. Colonic transit time (CTT), determined by the amount of ingested ROMs visualized with X-ray
2. Participant assessment of digestive symptoms in addition to bloating (abdominal pain, flatulence/gas and borborgymi/burbling/rumbling), assessed daily for 14 days (Day 0 to Day 14) with an eDiary together with the primary outcome
3. Defecation frequency and stool consistency, assessed daily for 14 days (Day 0 to Day 14) with an eDiary together with the primary outcome
4. Constipated-related PAC-SYM and PAC-Qol questionnaries, assessed at baseline (Day 0) and at the end of the intervention (Day 14)
5. Faecal microbial analysis, assessed at baseline (within Day -6 until Day 0), and at the end of intervention (within Day 8 until Day 14)
6. Overall product satisfaction, evaluated at the end of the intervention (Day 14)

Safety of the investigational product will be evaluated throughout the study on the basis of serious and non-serious adverse events, as outlined in Adverse Events.

Overall study start date
01/08/2015

Completion date
26/02/2016

Eligibility

Key inclusion criteria
1. Age 18 - 70
2. Obtained his/her informed consent after verbal and written information
3. Sufficient general health and orientation for participating in the study
4. Have a high probability for compliance with and completion of the study
5. Functional constipation or constipation predominant IBS according to Rome III criteria
6. Bowel movement frequency 1-3/week
7. Stool consistency 1-2 according to Bristol Stool Scale Form for most spontaneously passed stools
8. Self-reported bloating at least twice a week
9. No continuous use of probiotics or probiotic containing product or drug within 1 month prior to screening

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
152 total, 76 per group

Total final enrolment
156

Key exclusion criteria
1. Participation in a clinical trial with an investigational product or drug within 2 months prior to screening
2. Likeliness to be non-compliant with the protocol, or to be unsuitable to the study by the investigator for any reason
3. Planned major changes in life style (diet, exercise level, travelling)
4. Eating disorder
5. Pregnant or breastfeeding women; women planning to become pregnant during the study
6. Subject under administrative or legal supervision
7. Diagnosed or suspected organic gastrointestinal disease
8. Severely impaired general health including cancer and cancer therapy
9. Prior major abdominal surgery
10. Lactose intolerance if the subject does not follow a lactose-restricted diet
11. Previous anaphylaxis type reaction to any substance in composition of the study product
12. Consumption of or unwillingness to refrain from the use of commercial probiotics or prebiotics during the trial
13. Laxative use within 48 hours of screening and regular use of laxatives (rescue medication

allowed for intolerable symptoms during study)
14. Regular use of any drug or dietary supplement known to cause constipation as a common side effect (e.g. iron, opioids, sucralfate misoprostol, 5-HT#-antagonists, antacids with magnesium, calcium or aluminum, anti-diarrheal medication, anti-cholinergic agents, calcium supplements, tricyclic anti-depressants or NSAIDs) within 1 month prior to the study randomization
15. History of drug or alcohol abuse
16. Subject has been on antibiotics within 1 month of screening visit

Date of first enrolment
30/09/2015

Date of final enrolment
12/02/2016

Locations

Countries of recruitment
Ireland

Study participating centre
Atlantia Food Trials
Unit 2
Bridge Water House
Skehard Road
Cork
Ireland
T12 H2TK

Sponsor information

Organisation
Danisco Sweeteners Oy

Sponsor details
Sokeritehtaantie 20
Kantvik
Finland
FI-02460

Sponsor type
Industry

ROR
https://ror.org/02nqcmv36

Funder(s)

Funder type
Industry

Funder Name
Danisco Sweeteners Oy

Results and Publications

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

Intention to publish date
31/03/2018

Individual participant data (IPD) sharing plan
For data protection reasons, the trialists do not make public any information, coded or non-coded regarding the study participants. This coded information is being held in the company database which is in compliance with GDPR regulations.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		20/11/2017	20/11/2017	No	No
Results article	results	10/07/2019	29/05/2019	Yes	No