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Effect of the probiotic strain BB-12® on the gastrointestinal function of healthy adults

Submission date	Recruitment status	[_] Prospectively registered
23/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/02/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
21/09/2015	Digestive System	

Plain English summary of protocol

Background and study aims:
Probiotics are microorganisms, characterised by their ability to survive the passage through the gut. They are often found in milk products such as yogurt and also commonly used as food supplements. Regular consumption is believed to have a beneficial effect on the abdominal wellbeing and bowel habit. The aim in this study is to investigate whether a capsule with a specific probiotic microorganism can improve the general abdominal wellbeing more than a capsule that does not contain probiotics.

Who can participate?
Individuals aged 18–70 years who are have good general health but with some gastrointestinal complaints and a low defecation frequency.

What does the study involve?
Participants will be randomly allocated to one of three groups and must take the study product every day for 4 weeks. The study product is a capsule containing probiotics (high or low dose) or no probiotics (placebo). Participants will need to complete a diary in which they must record information about their bowel habits and discomfort for each day. Additionally, all study participants should complete questionnaires about physical activity, general quality of life and food habits twice during the study.

What are the possible benefits and risks of participating?
The consumption of the probiotic capsule could lead to a general improvement in the subject's gastrointestinal wellbeing and bowel habit. There are no known risks to participants taking part in this study.

Where is the study run from?
Clinical research centres: EUROFINS OPTIMED (France), OPTIMED (France), CRS Clinical Research Services Mannheim GmbH (Germany), CRS Clinical Research Services Mönchengladbach GmbH (Germany), CRS Clinical Research Services Kiel GmbH (Germany), Analyze & Realize AG (Germany), Leatherhead Food Research (UK) and SynteractHCR (Germany)

When is the study starting and how long is it expected to run for?
September 2010 to December 2012.

Who is funding the study?
Chr Hansen A/S (Denmark)

Who is the main contact?
Mrs Lillian Jespersen

Contact information

Type(s)
Scientific

Contact name
Mrs Lillian Jespersen

Contact details
Chr. Hansen A/S
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2970

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HND-GI-004

Study information

Scientific Title
The efficacy of 4 weeks supplementation with Bifidobacterium animalis subsp. lactis, BB-12® in a capsule on overall gastrointestinal well-being, stool frequency and gastrointestinal discomfort symptoms in healthy men and women with abdominal discomfort – a randomized, double-blind, placebo-controlled, parallel group study

Study objectives
To investigate the efficacy of daily consumption of the probiotic strain BB-12® for 4 weeks on the overall gastrointestinal wellbeing, stool frequency and gastrointestinal discomfort symptoms in healthy individuals with gastrointestinal discomfort

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Comité de Protection des Personnes Sud-Est IV (France), 16/09/2010, ref: 2010-A00958-31
2. Ethikkommission Schleswig-Holstein (Germany), 31/10/2011, ref: 155/11 (m)
3. Ethik-Kommission bei der Landesärztekammer Baden-Württemberg (Germany), 15/11/2011, ref: B-F-2011-076
4. Ethik-Kommission bei der Ärztekammer Nordrhein (Germany), 30/11/2011, ref: 2011405
5. Ethik kommission der Charité (Germany), 20/10/2011, ref: EA1/236/11
6. National Research Ethics Service Committee London (UK), 24/08/2011, ref: 11/LO/1246
7. Ethikkommission der Bayerischen Landesärztekammer (Germany), 24/09/2012, ref: mb BO 12044

Study design
Randomised double-blind placebo-controlled multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Low defecation frequency and abdominal discomfort

Interventions
Study products to be taken orally once daily for 4 weeks:
1. Capsule containing a high dose (10 billion colony-forming units [CFU]) of BB-12®
2. Capsule containing a low dose (1 billion CFU) of BB-12®
3. Placebo capsule with no probiotics

Intervention Type
Supplement

Primary outcome measure
1. Stool frequency will be measured with a completed Bristol Stool Form at baseline and each week during the intervention period
2. General abdominal discomfort will be measured each week during the intervention period by subject’s rating of general abdominal discomfort compared with before the study (markedly relieved, somewhat relieved, unchanged, somewhat worsened and markedly worsened)

Secondary outcome measures

Abdominal discomfort symptoms will be rated daily during the entire study with a Likert scale (0=no, 1=mild, 2=moderate, 3=severe and 4=unbearable) and results averaged for baseline and each week during the intervention period

Overall study start date
01/06/2010

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Healthy
2. Age 18–70 years
3. Body-mass index 19–35 kg/m2
4. General abdominal discomfort or complaints
5. A low defecation frequency

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1740

Key exclusion criteria
1. History of hypersensitivity to any of the ingredients of the study products
2. History of lactose intolerance
3. History or diagnosis of gastrointestinal disease, irritable bowel syndrome or complicated gastrointestinal surgery
4. Depressive disorder
5. Any physical abnormality or medical condition that could have an effect on gastrointestinal discomfort
6. Participation in any other clinical study
7. Not willing or able to provide written informed consent for participation in the study or for transmission of personal pseudonymised data
8. Women not willing or able to use a reliable contraceptive method
9. Pregnancy
10. Lactation
11. Wish to become pregnant

Date of first enrolment
01/09/2010

Date of final enrolment
01/11/2012

Locations

Countries of recruitment
England

France

Germany

United Kingdom

Study participating centre
EUROFINS OPTIMED
Gieres
France
38610

Study participating centre
OPTIMED
Lyon
France
69310

Study participating centre
CRS Clinical Research Services Mannheim GmbH
Mannheim
Germany
68167

Study participating centre
CRS Clinical Research Services Mönchengladbach GmbH
Mönchengladbach
Germany
41061

Study participating centre
CRS Clinical Research Services Kiel GmbH
Kiel
Germany
24105

Study participating centre
Analyze & Realize AG
Berlin
Germany
10369

Study participating centre
Leatherhead Food Research
Leatherhead
United Kingdom
KT22 7RY

Study participating centre
SynteractHCR
Clinical Unit
Munich
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80636

Sponsor information

Organisation
Chr. Hansen A/S

Sponsor details
Boege Alle 10-12
Hoersholm
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2970

Sponsor type
Industry

ROR
https://ror.org/01mv6bt66

Funder(s)

Funder type
Industry

Funder Name
Chr. Hansen A/S (Denmark)

Results and Publications

Publication and dissemination plan
The study results will be published in an international scientific journal in 2015.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/11/2015		Yes	No