

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

<b>Submission date</b> 23/01/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 04/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/09/2015	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## 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  
Boege Alle 10-12  
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Denmark  
2970

## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Other

## **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(s)**

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)

## **Key secondary outcome(s)**

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

## **Completion date**

31/12/2012

# **Eligibility**

## **Key inclusion criteria**

1. Healthy
2. Age 18–70 years
3. Body-mass index 19–35 kg/m<sup>2</sup>
4. General abdominal discomfort or complaints
5. A low defecation frequency

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

England

France

Germany

**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  
Germany  
80636

## Sponsor information

### Organisation

Chr. Hansen A/S

### ROR

<https://ror.org/01mv6bt66>

## Funder(s)

### Funder type

Industry

### Funder Name

Chr. Hansen A/S (Denmark)

## Results and Publications

### 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?
<a href="#">Results article</a>	results	28/11/2015		Yes	No

