

Control of *Helicobacter pylori* by a specific strain of *Lactobacillus reuteri*

Submission date 22/08/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/08/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 10/06/2014	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Infection with *H. pylori* bacteria is the cause of most stomach ulcers. The management of *H. pylori* infections is still a matter of discussion. Treatment options for *H. pylori* aiming at complete eradication of the infection include various combinations of proton pump inhibitor drugs combined with two to three antibiotics. This complex approach has high risks of side effects and patient non-compliance with the treatment. As there can be an interaction between *H. pylori* infections and mental stress, short-term reduction of the infection may be another viable option during stressful life events. This study will test whether supplementation with *Lactobacillus reuteri* bacteria decreases *H. pylori* infection.

Who can participate?

Men and women between the ages of 18 and 75 with an *H. pylori* infection.

What does the study involve?

Participants will be tested to find out whether they have antibodies against *H. pylori*. If they do, their infection state will be diagnosed by a breath test. If this test confirms an ongoing infection and no acute diseases or other potential reasons for exclusion from the study, participants will take tablets containing either dried *Lactobacillus reuteri* or a placebo (dummy) tablet, each for two weeks. After each two-week period, the breath test will be repeated.

What are the possible benefits and risks of participating?

If the *Lactobacillus reuteri* tablets reduce *H. pylori* infection, there may be a short-term benefit for participants. This does not mean an eradication of the *H. pylori* infection. There are no known risks related to the test product or the diagnostic procedures.

Where is the study run from?

University Hospital Charité in Berlin-Buch, under coordination from HealthTwist GmbH.

When is the study starting and how long is it expected to run for?

The study ran from September 2011 to September 2012.

Who is funding the study?
Lonza Ltd (Switzerland).

Who is the main contact?
Dr Andreas Busjahn
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Contact information

Type(s)
Scientific

Contact name
Dr Andreas Busjahn

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
In-vivo cross-over study to test impact of a specific strain of Lactobacillus reuteri (DSMZ17648 (Pylopass™ / Lonza) on infection by Helicobacter pylori as determined by 13C urea breath test

Study objectives
Reduction of H. pylori load as measured by 13C-UBT after two weeks of Pylopass™ supplementation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Charité, Berlin, 12/09/2011, ref: EA3/017/07

Study design

Single-center non-randomized interventional placebo-controlled cross-over study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Helicobacter pylori

Interventions

Lactobacillus reuteri (DSMZ17648 (Pylopass™ / Lonza) vs placebo

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

¹³C urea breath test is a semi-quantitative test for infection by H.pylori. Breath samples are taken before treatment, after 2 weeks of active treatment, and after two weeks of placebo. Samples are sent to a commercial lab for analysis.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/09/2011

Completion date

01/10/2012

Eligibility**Key inclusion criteria**

1. Aged 18 to 75 years
2. Male and female participants
3. Infection by H.pylori with by ^{13}C urea breath test ≥ 12

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

75 Years

Sex

Both

Target number of participants

20

Key exclusion criteria

1. Intake of any medication interfering with the action of the lactobacilli
2. Previous surgical procedures affecting stomach or small intestine with potential interference with the study, e.g. gastrectomy or gastric bypass, diabetes type 1 or 2
3. Familiar lipid metabolism diseases, liver disease, kidney insufficiency, autoimmune disease, organ transplantation
4. Weight changes >3 kg over the last 3 months
5. Eradication therapy
6. Lactose intolerance
7. Oral intake of antibiotics < 3 months ago
8. Intake of PPIs or H2 antagonists
9. Pregnancy or lactation
10. Alcohol or drug abuse
11. Psychiatric diseases
12. Participation at other clinical trials at the same time

Date of first enrolment

01/09/2011

Date of final enrolment

01/10/2012

Locations**Countries of recruitment**

Germany

Study participating centre
HealthTwist GmbH
Berlin
Germany
13125

Sponsor information

Organisation

Lonza Ltd (Switzerland)

Sponsor details

Scientific Marketing, Nutrition
Münchensteinerstrasse 38
Basel
Switzerland
4002

Sponsor type

Industry

Website

<http://www.lonza.com/>

ROR

<https://ror.org/002adfz67>

Funder(s)

Funder type

Industry

Funder Name

Lonza Ltd (Switzerland)

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