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Control of Helicobacter pylori by a specific strain of Lactobacillus reuteri

Submission date
22/08/2012

Recruitment status
No longer recruiting

Registration date
30/08/2012

Overall study status
Completed

Last Edited
10/06/2014

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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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 13C 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