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The effect of Lactobacilli on the immune system of healthy adults

Submission date
22/09/2011

Recruitment status
No longer recruiting

Registration date
28/09/2011

Overall study status
Completed

Last Edited
14/07/2015

Condition category
Haematological Disorders

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
It is a challenge to investigate the immune system (bodily process that protects against diseases) in healthy people. Currently, the best method is to vaccinate people and investigate how the immune system reacts. The probiotic (beneficial lactic acid bacteria) investigated in this study has previously been shown to have a beneficial effect on the immune system. The aim of this study is to use the similar vaccination model to study the beneficial effects of the study product on the immune system.

Who can participate?
To take part you need to be aged 18 to 60 years, in general good health.

What does the study involve?
You must consume the study product each day for 6 weeks. The study product is a milk drink containing probiotics, or an identical milk drink without probiotics (placebo). To assess the effect of the probiotics on the immune system, all study participants will be given the seasonal influenza vaccination for 2011-2012. To assess the response to the influenza vaccine blood samples will be collected 4 times during the study. In addition, all study participants should for the three months duration of the study complete a diary on symptoms of common cold and influenza and general quality of life.

What are the possible benefits and risks of participating?
As all participants will receive the seasonal influenza vaccination, a potential benefit of participating in the study is that you may be better protected against influenza during the 2011-2012 influenza season.
The study product is a food product with no adverse effects. The vaccine is the approved seasonal influenza vaccine for 2011-2012 which is considered safe.

Where is the study run from?
The study takes place at Harrison Clinical Research in Munich, Germany and at the University of Copenhagen, Denmark.

When is the study starting and how long is it expected to run for?
The study recruited participants from September to November 2011.

Who is funding the study?
Chr. Hansen A/S is funding the study.

Who is the main contact?
Mrs. Lillian Jespersen
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Contact information

Type(s)
Scientific

Contact name
Mrs Lillian Jespersen

Contact details
Boege Allé 10-12
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2970

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HND-IM-011

Study information

Scientific Title
The effect of Lactobacillus paracasei subsp. paracasei, L. casei 431® on immune response to influenza vaccination in healthy adult volunteers: a multi-center, randomized, placebo-controlled, parallel-group study

Study objectives
The study was designed to investigate the immune modulating properties of the probiotic strain L. casei 431® in an influenza vaccination model.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. The Ethical Committee of the Capital Region of Denmark, 12/09/2011, journal number H-1-2011-107
2. The Ethical Committee of the Bayerische Landesärztekammer, 13/09/2011, journal number 11075

Study design
Randomized double-blind placebo-controlled parallel-group multi-centre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

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
General immune defence

Interventions
Two different treatment arms are included in the study:
1. A milk drink containing the probiotic strain Lactobacillus paracasei ssp. paracasei, L. casei 431® in a dosage of minimum 1 billion Colony forming units (CFU)/DAY
2. A placebo milk drink

Study products to be taken orally once daily for six weeks.
A seasonal influenza vaccination for 2011/2012 will be given to all subjects after 3 weeks of supplementation with the study product.
Nine weeks follow-up after end of the supplementation phase.

Intervention Type
Biological/Vaccine

Primary outcome measure
Haemagglutinin inhibition titers in serum 3 weeks after the vaccination

Secondary outcome measures
Antigen-specific antibody response to the influenza vaccination 3 weeks after the vaccination

Overall study start date
30/09/2011

Completion date

30/04/2012

Eligibility

Key inclusion criteria
1. Men or women in a general good state of health, age 18-60 years both inclusive
2. Body mass index (BMI) 19-30 kg/m2
3. Provided voluntary written informed consent
4. No antibiotics during the run-in period
5. Subject has been able to abstain from fermented dairy products (such as yoghurts) as well as food and food supplements containing probiotics during the run-in period

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
Target number of participants: 1058 subjects, 529 in each arm.

Key exclusion criteria
1. Chronic immunological disease
2. No cancers within the past five years
3. Influenza vaccination current season or has already suffered from influenza during the current season
4. Acute disease requiring treatment
5. Use of immunosuppressant medication
6. Lactose intolerance or milk protein allergy
7. Hypersensitivity to any of the components of the vaccine
8. Recent complicated gastrointestinal (GI) surgery that may have an impact on GI tract function
9. Oral antibiotics within one month prior to the screening visit
10. Elite athletes
11. Participation in another clinical trial within the past month
12. For pre-menopausal women: pregnant or lactating, or wish to be pregnant during the study and not willing to use reliable contraceptive methods

Date of first enrolment
30/09/2011

Date of final enrolment

01/11/2011

Locations

Countries of recruitment
Denmark

Germany

Study participating centre
Boege Allé 10-12
Hoersholm
Denmark
2970

Sponsor information

Organisation
Chr. Hansen A/S (Denmark)

Sponsor details
Boege Allé 10-12
Hoersholm
Denmark
2970

Sponsor type
Industry

Website
http://www.chr-hansen.com

ROR
https://ror.org/01mv6bt66

Funder(s)

Funder type
Industry

Funder Name
Chr. Hansen A/S (Denmark)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No