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Safety and efficacy of insoluble (1,3)-(1,6)-beta-glucan made from brewers yeast (Saccharomyces cerevisiae)

Submission date
30/07/2012

Recruitment status
No longer recruiting

Registration date
03/08/2012

Overall study status
Completed

Last Edited
05/10/2016

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
Beta-glucans are sugars found in the cell walls of brewers' yeast, fungi, and some bacteria. Due to its immune system stimulating properties, beta-glucan may have an effect on the incidence of common cold (a mild viral infection of the nose, throat, sinuses and upper airways). The aim of this study is to investigate the effectiveness and safety of the beta-glucan extract Yestimun® in people who are more susceptible to the common cold.

Who can participate?
Healthy males and females aged 18-70 who have had at least three common cold infections within the last 6 months

What does the study involve?
During the study period of 16 weeks, participants are randomly allocated to consume a capsule of either Yestimun or a placebo (dummy tablet) each with breakfast and supper. Participants attend three visits: at the start of the study, after 8 weeks and at the end after 16 weeks. The number, severity and duration of colds, use of antibiotics and analgesics (painkillers), and side effects are assessed in both groups.

What are the possible benefits and risks of participating?
Participants may benefit from a reduced incidence of common cold, and there are no risks expected.

Where is the study run from?
The study is conducted in seven study centres in Berlin, Germany

When is the study starting and how long is it expected to run for?
October 2010 to May 2011

Who is funding the study?
Leiber GmbH (Germany)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LEI/K/00810

Study information

Scientific Title
Double-blind, randomized, placebo-controlled clinical study to evaluate efficacy and safety of Yestimun® in subjects with increased susceptibility to common cold

Study objectives
Due to the immune-modulating properties of yeast beta-glucan, the number of common cold episodes is expected to be decreased during the study period in the verum study arm compared to the placebo study arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Charité - Universitaetsmedizin Berlin, Campus Charité Mitte), 14/10/2010, ref: EA1/221/10

Study design
Double-blind randomized placebo-controlled multi-centre clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Immune function

Interventions
Subjects were randomly assigned to receive a total of 900 mg of either Yestimun® or placebo, each provided in two capsules per day, which were consumed at breakfast and supper.

During the study period of 16 weeks, a total of three routine visits were performed: at baseline, after 8 weeks and at the end after 16 weeks. In addition, one episode visit was conducted on the 5th day of each cold episode.

A cold episode was defined by having (any of) the following symptoms: headache, joint pain, sore throat, difficulty swallowing, hoarseness, coughing, watery nasal discharge, nasal congestion, cold related sleeping difficulties, and body temperature above 38°C. During an episode, the subjects recorded and assessed their cold symptoms in the subject diary, for a period of 14 days. The diaries were checked by the investigators at the Episode Visits of each episode.
At study end (Termination Visit), the investigators and the subjects assessed the global efficacy and tolerability of the investigational product. At the start and end of the study, subjects recorded their eating habits in a diet diary.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Yestimun®

Primary outcome measure

Reduction of number of cold episodes during the study period in the Yestimun® study arm compared to placebo study arm

Secondary outcome measures
1. Severity of cold episodes (total sum score during the entire episode)
2. Duration of cold episodes (based on subject diary)
3. Severity of colds at episode start (total score on day 1 and day 2)
4. Severity of colds on the day of the Episode Visit (CRF)
5. Use of antibiotics and analgesics (subject's diary)
6. Global assessment of efficacy and tolerability
7. Assessment of adverse events
8. Assessment of sick leave days

Overall study start date
15/10/2010

Completion date
12/05/2011

Eligibility

Key inclusion criteria
1. Age: ≥ 18 years (child-bearing females had to agree to use appropriate birth control methods)
2. At least three common cold infections within the last six months
3. Written consent of the subject to study participation, subject understands the requirements and is willing to comply

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
224

Key exclusion criteria
1. Acute infection of the upper airways (e.g. acute bronchitis)
2. Chronic upper airway disease (e.g. chronic bronchitis, tonsillitis or asthma)
3. Chronic cough of any origin
4. Chronic rhinitis (vasomotor or allergic rhinitis)
5. Congenital or acquired immunodeficiency disease (e.g. HIV infection)
6. Acute or chronic diarrhea

7. Severe organ or systemic diseases
8. Suspected swine flu or influenza
9. Body temperature above 37.5°C
10. Vaccination against influenza or swine flu within 21 days prior to study start
11. Known hypersensitivity to ingredients of the investigational product
12. Pregnancy and lactation
13. Use of immunosuppressants
14. Use of immunostimulants (e.g. Echinacea) within the last 14 days prior to study start
15. Use of antibiotics within the last 14 days prior to study start
16. Alcohol/drug abuse; drug addiction
17. Simultaneous participation in another clinical trial or participation in a clinical trial within the last 4 weeks
18. Regular use of other yeast preparations
19. Incertainty regarding compliance

Date of first enrolment
15/10/2010

Date of final enrolment
12/05/2011

Locations

Countries of recruitment
Germany

Study participating centre
analyze & realize ag
Berlin
Germany
13467

Sponsor information

Organisation
Leiber GmbH (Germany)

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Hafenstraße 24
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Sponsor type
Industry

Website
http://www.leibergmbh.de/

ROR
https://ror.org/011bzst67

Funder(s)

Funder type
Industry

Funder Name
Leiber GmbH (Germany)

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