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Improved immune defense by a proprietary larch arabinogalactan

Submission date	Recruitment status	[_] Prospectively registered
18/05/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/06/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/10/2016	Infections and Infestations	

Plain English summary of protocol

Background and study aims
The common cold is a mild viral infection of the nose, throat, sinuses and upper airways. The aim of this study is to find out whether ResistAid™ (arabinogalactan), a sugar derived from larch trees, helps to decrease the incidence of the common cold by boosting the immune system.

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

What does the study involve?
Participants are randomly allocated to consume a sachet of ResistAid™ or placebo (dummy drug) daily with breakfast over a course of 12 weeks. Participants attend three visits: at the start of the study, after 6 weeks and at the end after 12 weeks. Additionally, if a cold occurs, there are two extra visits at the start and on the fifth day of the cold. Participants recorded their cold symptoms in a diary. The number, severity and duration of colds 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?
Analyze & Realize AG (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?
Lonza Ltd (Switzerland)

Who is the main contact?
Dr Linda Böhme
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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
LON/K/01309

Study information

Scientific Title
Double-blind, randomized, placebo-controlled clinical study to evaluate the immune-enhancing properties of a proprietary larch arabinogalactan (ResistAid™) by assessing the incidence of common cold

Study objectives
The incidence of common cold during the study period is expected to be decreased 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), 12/10/2010, ref: EA1/208/10

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
ResistAid™ study arm compared to placebo study arm

Intake of one sachet (4.5g) daily with breakfast. A total of three basic visits were performed: Visit 1 at study start (=baseline), Control Visit after 6 weeks and Termination Visit after 12 weeks. Additionally, if a cold episode occurred, an Episode Visit was performed at start and on the 5th day of each 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 second Episode Visit 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. Further, the safety laboratory parameters as well as special laboratory parameters (leukocyte differentiation) were assessed at baseline and end of study.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Larch arabinogalactan (ResistAid™)

Primary outcome measure
Number of cold episodes during the study period

Secondary outcome measures
1. Duration of cold episodes (based on subject diary)
2. Episode intensity assessed per change of the total sum score after 5 days compared to start of episode (first Episode Visit), based on case report form (CRF) and subject diary
3. Episode intensity at start of episode (sum score on Day 1 based on subject diary, i.e. at first Episode Visit based on CRF)
4. Global assessment of efficacy and tolerability
5. Assessment of adverse events
6. Assessment of laboratory parameters including leucocyte differentiation
7. Assessment of eating habits based on a 3-day-record

Overall study start date
13/10/2010

Completion date
05/05/2011

Eligibility

Key inclusion criteria
1. Age 18 - 70 years (child-bearing females had to agree to use appropriate birth control methods)
2. Recurrent infections of upper airways (at least 3 episodes in half-year according to subjects statement)
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
200

Key exclusion criteria
1. Acute infection of the upper airways
2. Chronic upper airways disease (e.g. chronic bronchitis or asthma)
3. Suspected influenza or swine flu
4. Body temperature above 38°C
5. Vaccination against influenza or swine flu within 21 days before study start
6. Serious organ or systemic diseases
7. Body mass index above 30

8. Clinically significant abnormal laboratory parameters (values outside of reference range)
9. Known sensitivity to the ingredients of the investigational product
10. Inborn or acquired immune deficiency disease (e.g. HIV infection)
11. Pregnancy and nursing
12. Use of following medication:
12.1. Immunosuppressive agents
12.2. Immunostimulating agents, e.g. Echinacea
12.3. Local oral and pharyngeal treatment
12.4. Antibiotics within 14 days before study start
13. Drugs, alcohol and medical abuse
14. Use of prebiotics and probiotics (e.g. yogurt, drinks, supplements)
15. Participation in another clinical study at or within 30 days before study start
16. Inability to comply with study requirements

Date of first enrolment
13/10/2010

Date of final enrolment
05/05/2011

Locations

Countries of recruitment
Germany

Study participating centre
Analyze & Realize AG
Berlin
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13467

Sponsor information

Organisation
Lonza Ltd (Switzerland)

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Sponsor type

Industry

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2013		Yes	No