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Immunomodulatory effects of a proprietary Arabinogalactan extract

Submission date 21/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2009	**Overall study status** Completed	
Last Edited 05/11/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LONZ1000

Study information

Scientific Title

Immunomodulatory effects of a proprietary Arabinogalactan extract: a randomised double-blind placebo controlled parallel group study

Study objectives
The hypothesis of this study is that ingestion of larch arabinogalactan will enhance immune function by increasing the antibody response in healthy volunteers to the 23-valent pneumonia vaccine.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB approval was obtained from the Copernicus Group (Cary, NC) on the 2nd September 2008 (ref: MED4-08-256)

Study design
Randomised double-blind placebo controlled parallel group study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Immune response to the 23-valent pneumococcal vaccine

Interventions
This is a randomised double-blind placebo controlled parallel group study with 45 healthy adults who had not previously had the pneumonia vaccine. The study was conducted at a single site Medicus Research clinical Research Center, Northridge, CA, USA.

Resistaid™ is an arabinogalactan extracted from the bark of the Larch tree (Larix spp., mostly Larix occidentalis; Lonza, Inc., Allendale, NJ). The placebo was maltodextrin (Maltin M100). The test product and the placebo were administered by mixing the powders into a beverage of the subject's choice for a maximum period of 72 days. The subjects were advised to take their dosage (4.5 g) once a day in the morning with breakfast.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Arabinogalactan extract (Resistaid™)

Primary outcome measure
Measurements of:
1. Plasma levels of pneumococcal IgG (subtypes 4, 6B, 9V, 14, 18C, 19F and 23F; enzyme-linked immunosorbent assay [ELISA])
2. Salivary IgA (ELISA)
3. Peripheral white blood cell counts (lymphocytes, neutrophils, etc.,)
4. Plasma complement (C3 and C4)
5. Cytokine levels (epithelial neutrophil-activating peptide [ENA]-78, eotaxin, granulocyte monocyte colony stimulating factor [GM-CSF], interferon-gamma [IFNg], interleukin [IL]-10, IL-12P40, IL-1RA, IL-2, IL-4, IL-5, IL-6, IL-8, monocyte chemotactic protein [MCP]-1, MCP-3, platelet-derived growth factor [PDGF]-BB, tumour necrosis factor [TNF]-alpha A and leptin)

All outcomes measured at baseline, day 30, day 51, and day 72.

Secondary outcome measures
Oxidative stress via F2 isoprostance in urine. All outcomes measured at baseline, day 30, day 51, and day 72.

Overall study start date
01/08/2008

Completion date
01/12/2008

Eligibility

Key inclusion criteria
1. Aged 18 to 65 years, either sex
2. Had a Body Mass Index (BMI) greater than 18 kg/m^2 and less than 30 kg/m^2 at screening
3. Agreed to all study visits and visit procedures
4. Agreed to use appropriate forms of birth control if females of child bearing potential
5. Agreed not to initiate/change any exercise or diet programs during the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Previously had the pneumococcal vaccine
2. Had allergies to the test product
3. Had any major systemic, inflammatory or chronic disease
4. Had any active infection or infection in the past month requiring antibiotics or anti-viral medication
5. Used immunosuppressive drugs in the prior 5 years
6. Known alcohol or drug abuse
7. Were pregnant or lactating
8. Had any medical condition which in the opinion of the investigator might interfere with the subject's ability in the trial

Date of first enrolment
01/08/2008

Date of final enrolment
01/12/2008

Locations

Countries of recruitment
United States of America

Study participating centre
18250 Roscoe Blvd. Suite 240
Northridge
United States of America
91325

Sponsor information

Organisation
Lonza, Inc (USA)

Sponsor details
90 Boroline Road
Allendale, NJ
United States of America
07401

Sponsor type
Industry

Website
http://www.lonza.com

ROR
https://ror.org/04g4p0a45

Funder(s)

Funder type
Industry

Funder Name
Lonza, Inc (USA)

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	26/08/2010		Yes	No