

Immunomodulatory effects of a proprietary Arabinogalactan extract

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design

Interventional

Study design

Randomised double-blind placebo controlled parallel group study

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Oxidative stress via F2 isoprostane in urine. All outcomes measured at baseline, day 30, day 51, and day 72.

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/m² and less than 30 kg/m² 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

ROR

<https://ror.org/04g4p0a45>

Funder(s)

Funder type

Industry

Funder Name

Lonza, Inc (USA)

Results and Publications

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