# Immunomodulatory effects of a proprietary Arabinogalactan extract

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

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

Dr Jay Udani

#### Contact details

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

## 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)

#### Study design

Randomised double-blind placebo controlled parallel group study

#### Primary study design

Interventional

#### 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<sup>™</sup> 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 isoprostance 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/m<sup>2</sup> and less than 30 kg/m<sup>2</sup> 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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults26/08/2010YesNoParticipant information sheetParticipant information sheet11/11/202511/11/2025NoYes