# Validation study of the immunomodulatory effects of ResistAid™

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
05/04/2011	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/04/2011	Completed	Results
Last Edited	t Edited Condition category	Individual participant data
06/09/2011	Haematological Disorders	Record updated in last year

# 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

LONZ1400

# Study information

#### Scientific Title

Validation study of the immunomodulatory effects of ResistAid™: a randomised, double-blind, placebo-controlled, dose-finding study

#### **Acronym**

LONZ1400

#### **Study objectives**

ResistAid™ will enhance the immune response to a standardised antigenic challenge (Tetanus vaccine and Influenza vaccine) in a dose dependent manner compared with placebo.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Copernicus Group IRB (Cary, NC) approved on 10th February 2010

#### Study design

Randomised double-blind parallel group clinical controlled trial

#### Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

**Immunomodulation** 

#### **Interventions**

There are 3 arms to the study. Based on the randomisation, subjects will be assigned to ResistAid™1.5g, ResistAid™4.5g, Placebo (Maltodextrin)

# Intervention Type

Drug

#### Phase

Not Applicable

# Drug/device/biological/vaccine name(s)

ResistAid™

#### Primary outcome(s)

Immune responses will be measured by Tetanus IgG

These serum markers will be measured upon screening, and again 15 days and 30 days after the vaccines have been administered.

# Key secondary outcome(s))

Immune responses will be measured by:

Influenza A IgM

Influenza A IgG

Influenza B IgM

Influenza B IqG

These serum markers will be measured upon screening, and again 15 days and 30 days after the vaccines have been administered.

# Completion date

# **Eligibility**

# Key inclusion criteria

- 1. Subjects must be between 18-65 years of age
- 2. Subject is willing to maintain his habitual food and beverage intake (other than substitution of study food for similar products) and physical activity patterns throughout the study period
- 3. Body mass index (BMI) between 18 and 30 kg/m2
- 4. Judged by the Investigator to be in general good health on the basis of medical history
- 5. Subject understands the study procedures and signs forms providing informed consent to participate in the study and authorisation for release of relevant protected health information to the study investigator
- 6. Females must agree to use approved birth control methods during the study
- 7. Subjects must not have had the Influenza vaccine for the 2009-2010 flu season
- 8. Subjects must not have had the Tetanus vaccine within the last 5 years

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

65 years

#### Sex

All

#### Key exclusion criteria

1. Subjects with any history of immune system disorder or auto-immune disorder including but not limited to the following:

Acquired immune deficiency syndrome (AIDS), human immunodeficiency virus (HIV), ankylosing spondylitis, chronic fatigue syndrome, CREST syndrome, crohns disease, dermatomyositis, fibromyalgia, graves disease, hashimotos thyroiditis, lupus, multiple sclerosis, myasthenia gravis, pernicious anaemia, polyarteritis nodosa, primary biliary cirrhosis, psoriasis, reynauds syndrome, rheumatoid arthritis, sarcoidosis, scleroderma, sjogrens syndrome, temporal arthritis, ulcerative colitis and vitiligo

- 2. Known allergy or sensitivity to any ingredients in the study products
- 3. Subjects with history of using diabetic medications during the last 4 weeks to start of study
- 4. Subjects with history of using insulin during the last 12 weeks to start of study
- 5. Any active infection, or infection in the last month requiring antibiotics, anti-viral medication or hospitalisation
- 6. Subjects with active eating disorder including anorexia nervosa, bulimia and/or obsessive

compulsive eating disorders

- 7. Subjects with untreated significant depression or other psychiatric disease noted during the initial screening. Subjects with stable depression who are receiving medication and/or therapy may be included
- 8. Subjects with unstable coronary artery disease, unstable congestive heart failure, stroke, unstable arrythmia, or uncontrolled hypertension
- 9. Subjects who are pregnant or breast-feeding
- 10. Subjects with history of seizure
- 11. Subjects on anticoagulation therapy
- 12. Recent history of (within 12 months) or strong potential for alcohol or substance abuse
- 13. Subjects with inflammatory bowel disease (ulcerative colitis or crohns disease)
- 14. Subjects with a history of perforation of the stomach or intestines
- 15. Subjects with brain and/or spinal cord injury
- 16. Untreated or unstable hypothyroidism
- 17. History or presence of cancer in the last 5 years, except for non-melanoma skin cancer
- 18. Use of any immunosuppressive drugs in the last 5 years
- 19. Steroids, biologics, etc
- 20. Any physical trauma in the last 4 months (including but not limited to motor vehicle accident or any physical injury)
- 21. Surgery within the last 6 months
- 22. Any clinically significant burn within the last 6 months
- 23. Current use of Insulin or use of Insulin in the past 3 years
- 24. Weight loss of more than or equal to 20 pounds in the last 3 months
- 25. Oestrogensare allowed as long as there has been no change in the dose or frequency in the last 6 months
- 26. Subjects with a history of symptomatic hypoglycemia in the past 1 month
- 27. Abnormal physical examination
- 28. Participation in a clinical study with exposure to any non-registered drug product within 30 days prior
- 29. Individual has a condition the Investigator believes would interfere with his or her ability to provide informed consent, comply with the study protocol, which might confound the interpretation of the study results or put the person at undue risk
- 30. Subjects unable to understand or follow the study protocol

#### Date of first enrolment

28/05/2010

#### Date of final enrolment

09/12/2010

# Locations

#### Countries of recruitment

United States of America

# Study participating centre

#### 18250 Roscoe Blvd.

Northridge United States of America 91325

# Sponsor information

# Organisation

Lonza (USA)

#### **ROR**

https://ror.org/04g4p0a45

# Funder(s)

# Funder type

Industry

#### **Funder Name**

Lonza (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?

Participant information sheet
Participant information sheet
11/11/2025 No Yes