ISRCTN12127589 https://doi.org/10.1186/ISRCTN12127589

Validation study of the immunomodulatory effects of ResistAid™

Submission date	Recruitment status	[ ] Prospectively registered
05/04/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/04/2011	Completed	[ ] Results
Last 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

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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

Primary study design
Interventional

Study design
Randomised double-blind parallel group clinical controlled trial

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

Completion date

09/12/2010

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