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Evaluation of immune modulation by beta-glucan, a soluble dietary fiber derived from reishi mushroom in healthy adult volunteers, a systemic clinical trial

Submission date
25/10/2022

Recruitment status
No longer recruiting

Registration date
31/10/2022

Overall study status
Completed

Last Edited
20/04/2023

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
To study how beta glucan, a soluble fiber isolated from an edible mushroom (Reishi, G. lucidum) can help fortify a healthy person's immune system.

Who can participate?
Healthy volunteers aged 18 to 55 years.

What does the study involve?
The study involves a simple, systemic regimen of taking the intervention/placebo dose (orally) once a day. Two blood drawn at the beginning and conclusion of the study.

What are the possible benefits and risks of participating?
Participants may feel more energetic and have a stronger resistance when stressed/under the weather. Risk may include minor allergic reaction if allergic to mushrooms, however, this should be excluded during the inclusion period.

Where is the study run from?
Super Beta Glucan Inc., Biomedical Research Division (USA)

When is the study starting and how long is it expected to run for?

Who is funding the study?
Super Beta Glucan Inc., Biomedical Research Division (USA)

Who is the main contact?
Dr Sherwin Chen, sherwinc@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRB00001145

Study information

Scientific Title
Randomized, placebo-controlled clinical study for the evalutation of immune modulation by Immulink MBG (Beta 1-3; 1-6 D-glucan; Poly-(l-6)-β-D-glucopyranosyl-(l,3)-β-D-glucopyranose) in healthy adult volunteers

Study objectives
To investigate the effect of orally administered Beta 1-3; 1-6 D-glucan derived from G. lucidum on various biomarkers and to explore the immunomodulatory mechanisms among a healthy adult population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2019, Glytheron IRB (24552 Raymond Way, Unit 54, Lake Forest, CA 92609, United States; +1 949-878-5800; IRB@glytheron.org), ref: NTUH00000336/ IRB00001145

Study design
Randomized double-blinded placebo-controlled multicenter clinical study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
The effect of orally administered Beta 1-3; 1-6 D-glucan in healthy volunteers

Interventions
Subjects were randomly assigned, through randomly permuted blocks generated by a random number generator (SPSS software version 22), to either the intervention group (200 mg of beta glucan in a capsule) or a placebo group (200 mg of dextrose monohydrate in a capsule) upon enrollment. Subjects began taking the intervention or placebo at Day 0, week 1 following completing the first venous peripheral blood sample collection. Subjects were provided with 84 days of supply and were instructed to take the test article on SID basis. Dosing was 200 mg of placebo or intervention dose (1 capsule) per day for consecutive 84 days (12 weeks). Subjects were instructed to self-administer the allotted dose once daily in the morning before or while having breakfast, for the entire 84 days. An interim safety monitoring will take place from Day 43 to Day 45 via phone calls when deemed necessary by the DSMB. At the end of the test article administration period (day 84, week 12), venous peripheral blood samples were collected to analyze for the following parameters including Total lymphocytes, CD3+, CD4+, CD8+, Natural Killer (NK) cell counts, NK cell mediated cytotoxicity, IgA, Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Creatinine, Red Blood Cell (RBC), Hemoglobin (HB), Hematocrit (HCT) and Platelet Counts.

Intervention Type
Supplement

Primary outcome measure
Serum biomarkers including CD3+, CD4+, CD8+ T and NK cells counts, CD4/Cd8 Ratio, NK-cell cytotoxicity, immunoglobulin A (IgA) (Serum) using serum samples at baseline (Day 0, week 1) and Day 84, week 12

Secondary outcome measures
Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Creatinine, Red Blood Cell (RBC), Hemoglobin (HB), Hematocrit (HCT) and Platelet Counts using serum samples at baseline (Day 0, week 1) and Day 84, week 12

Overall study start date
30/03/2019

Completion date
08/01/2020

Eligibility

Key inclusion criteria
1. Male and female (unpregnant) subjects between 18 and 55 years of age, inclusive.
2. Participants willing to refrain from taking any non-essential medication from the onset of the study until follow up evaluation, with the exception of medical emergency.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Total final enrolment
173

Key exclusion criteria
1. Participant who was not able to give adequate informed consent; without the legal ability to act; who lack sufficient understanding or capacity to make or communicate responsible decisions.
2. Participants who were unable to adhere to the study protocols.
3. Participants participated in any other research study.
4. Participants who were current smoker or tobacco related product user.
5. Women who are pregnant or nursing.
6. Participants with status asthmaticus.
7. Participants with uncontrolled hypertension, peripheral vascular disease, hepatic diseases (with or without abnormal liver enzymes), or history of hyponatremia or hyperthermia.
8. Participants with evidence or history of significant hematological, endocrine, cerebrovascular, cardiovascular, coronary, pulmonary, renal gastrointestinal, immunocompromising, or neurological disease, including seizure disorder.
9. Participants who have had organ transplantation(s), under treatments of immunosuppressant medications, diagnosed with cancer or any other malignancy, or type I/II diabetes mellitus.

10. Participants who have had any life threatening allergic event in the past.
11. Participants or have allergy events to dextrose monohydrate.
12. Participants taking medications, mainly glucocorticoids.

Date of first enrolment
30/03/2019

Date of final enrolment
29/08/2019

Locations

Countries of recruitment
Taiwan

Study participating centre
TYB Biomedical Research Center
No. 2, Ln. 315, Sec. 2
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Zhonghe Dist.
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Sponsor information

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Sponsor type
Research organisation

Funder(s)

Funder type

Industry

Funder Name
Super Beta Glucan Inc., Biomedical Research Division

Results and Publications

Publication and dissemination plan
Planned publication in an SCI peer reviewed journal

Intention to publish date
02/01/2023

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study will be published as a supplement to the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/02/2023	20/04/2023	Yes	No