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The effects of Muno-IgYTM on immune function in healthy adult volunteers

Submission date
08/12/2022

Recruitment status
No longer recruiting

Registration date
12/01/2023

Overall study status
Completed

Last Edited
19/06/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The purpose of the study is to investigate the potential of the test product Muno-IgYTM on minimizing the incidence of upper respiratory tract infections (URTIs) (such as the common cold) in healthy adults over a 12-week period during cold and flu season
The test product is Muno-IgYTM. The test product is a natural health product derived from eggs, that is comprised of 75% egg yolk protein of which not less than 30% is the active ingredient immunoglobulin Y (IgY). The placebo will look identical to the test product. The term study product used in this document will refer to both the test product and placebo.

Who can participate?
Healthy volunteers aged 35 - 65 years

What does the study involve?
Study products should be consumed once daily (2 capsules) and are recommended to be taken in the morning with or without food. You should keep the study products out of the reach of children.
The study products will be provided to you in the form of a capsule. You will consume your first dose of the study product at the clinic on Day 1. You will continue taking the study product daily over the next 12 weeks at home, unless otherwise indicated, up to the end of the study visit [Visit 6, Day 85 ± 3].

What are the possible benefits and risks of participating?
There are no direct benefits from participating in this study. The information obtained from the results of the study regarding the effects of the test product on immunity may benefit others.
Oral consumption of the test product ingredients may lead to side effects such as bloating, diarrhea, skin rash, and intestinal gas.
Due to the exercise challenge, potential risks include muscle strains/pulls, injury, shortness of breath, irregular heartbeats, and abnormal blood pressure responses.
Due to the blood sample, potential risks include discomfort or bruising at the puncture site and infection, although uncommon.

Where is the study run from?
Nutrasource Pharmaceutical and Nutraceuticals Inc. (Canada)

When is the study starting and how long is it expected to run for?
May 2022 to July 2023

Who is funding the study?
IGY Immune Technologies & Life Sciences, Inc. (Canada)

Who is the main contact?
Stephanie Recker, srecker@nutrasource.ca

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
I01-22-01-T0033

Study information

Scientific Title
A two-arm randomized, double-blind, placebo-controlled, pilot study to evaluate the effects of Muno-IgYTM on immune function in healthy adult volunteers

Acronym
MunoIgYTM

Study objectives

The primary objective of this study is to determine differences in the incidence of self-reported URTIs over 12 weeks in the TP group compared to the placebo group

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 09/12/2022, Sterllng IRB (6300 Powers Ferry Rd., Suite 600-351, Atlanta, 30339, United States of America; +1 (0)678- 501 7833; Selam.Ghebru@sterlingirb.com), ref: 10578

Study design
Interventional randomized double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Prevention of cold or flu

Interventions
This is a two-arm randomized, placebo-controlled, double-blind, pilot study to assess the effects of Muno-IgYTM on the immune response in healthy adult volunteers, measured by incidence of URTIs over a 12-week period. As secondary outcomes, the duration and severity of URTIs will also be determined through daily dairy entries. Relative abundance of microbial species in fecal samples will also be measured after 12 weeks of supplementation. Additionally, changes from baseline in markers of inflammation and levels of IgA, cortisol, and LBP in serum will be assessed after 4 and 12 weeks of supplementation. To assess the TP's effect on markers of inflammation and muscle damage in response to an exercise challenge, these markers will be measured pre-exercise and 1h, 2h, 24h and 72h post-exercise. Changes in serum levels of IgA, random cortisol and LBP will also be assessed 24h post-exercise. There will be two study groups, including one TP group and one placebo group. Each group will have 14 participants for a total of 28 participants.

The study will last approximately 16 weeks (four months) for each participant. The study will include a screening visit followed by a screening period lasting up to 28 days and no less than 7 days in duration, a baseline visit on Day 1, four interim visits, and an EOS visit on the day after 12 weeks (84 ± 3 days) of study product use. The study will include a total of six in-person visit days: screening (Visit 1), baseline (Visit 2), Visit 3, Visit 4 (24 ± 1h post-exercise), Visit 5 (72 ± 1h post-exercise), and EOS at Week 12 (Visit 6). There will also be one remote check-in phone call at Week 8. Efficacy outcome measures include incidence, severity, and duration of URTIs, relative microbial abundance, blood markers of inflammation, markers of muscle damage, serum IgA measurements, random serum cortisol measurements and serum LBP measurements, which will be assessed at baseline, Visit 3 prior to an exercise challenge, EOS, and after the exercise challenge at Visits 3, 4 and 5 where applicable.

Intervention Type
Biological/Vaccine

Phase
Phase II

Drug/device/biological/vaccine name(s)
Immunoglobulin Y

Primary outcome(s)
Immune function measured by incidence of URTI evaluated from participant diaries over a 12-week period

Key secondary outcome(s))
1. Severity of URTIs measured by number of days of missed work/school due to URTI-related symptoms as reported by daily diaries over a 12-week period
2. Duration of URTIs measured by duration of URTI related symptoms as reported by participants in daily diaries over a 12-week period
3. Gut microbiome measured by relative abundance of microbial species in fecal samples after 12 weeks as assessed by 16S rRNA sequencing
4. Inflammation measured by change from baseline in blood markers of inflammation (TNF-α, IL-6, IL-10 and IL-1-β) after 4 and 12 weeks of supplementation
5. Immune response measured by change from baseline in serum IgA measurements after 4 and 12 weeks of supplementation
6. Cortisol measured by random serum cortisol after 4 and 12 weeks
7. Lipopolysaccharide binding protein (LBP) measured by LBP levels after 4 and 12 weeks of supplementation
8. Post-exercise effect of TP on muscle damage and inflammation measured by serum CRP, TNF-α, IL-6, IL-10, IL-1-β, CPK and LDH pre-exercise and 1h, 2h, 24h and 72h post-exercise
9. Post-exercise effect of TP on immune response, cortisol levels and LBP measured by serum IgA, random cortisol and LBP at 24h post-exercise

Completion date
17/07/2023

Eligibility

Key inclusion criteria
1. Healthy adult participants who are 35 to 65 years of age (inclusive).
2. Has a body mass index (BMI) between 18.5 to 29.9 kg/m² (inclusive).
3. In good general health (no uncontrolled diseases or conditions) as deemed fit by the investigator and are able to consume the study product.
4. Self-reported at least one incident of a URTI (e.g., common cold) in the last 6 months. If participants have a URTI between screening (Visit 1) and baseline (Visit 2), they must be asymptomatic by one week prior to baseline.
5. Is planning to be employed and/or attend school (minimum 20h per week) for the duration of the study period.
6. Frequent exposure to an environment that may put them at risk of contracting URTIs (i.e., health care or childcare worker, commuter using high density regular use of public transportation, and other populations that participants are regularly in public areas for the majority of their workday and use little to no personal protective equipment).
7. Appropriate for exercise as determined by the Physical Activity Readiness Questionnaire (PAR-Q).
8. Non-smokers (including nicotine vaping) and has not used nicotine-containing products for

more than three months prior to baseline. Note: Non-smoker is defined as someone who does not habitually/regularly use products containing nicotine.
9. Individuals with childbearing potential must agree to practice an acceptable form of birth control for a certain timeframe prior to the first dose of the study product and throughout the study, including:
9.1. Use for at least three months prior to the first dose of study product: hormonal contraceptives including oral contraceptives, hormone birth control patch (e.g., Ortho Evra), vaginal contraceptive ring (e.g., NuvaRing), injectable contraceptives (e.g., Depo-Provera, Lunelle), hormone implant (e.g., Norplant System), or intrauterine devices (e.g., Mirena); or
9.2. Use for at least one month prior to the first dose of study product: double-barrier method, non-hormonal intrauterine devices (i.e., copper), or complete abstinence from sexual intercourse that can result in pregnancy; or
9.3. Vasectomy of partner at least six months prior to the first dose of study product
Individuals with the potential to impregnate others must agree to use condoms or other acceptable methods to prevent pregnancy throughout the study. Complete abstinence from sexual intercourse that can result in pregnancy is also acceptable.
10. Agree to refrain from certain restricted concomitant treatments in the respective timeframe as defined in the study protocol.
11. Has maintained consistent lifestyle, dietary (including supplement intake) and exercise habits for the last three months prior to screening and agree to maintain lifestyle, dietary and exercise habits throughout the study.
12. Agree to refrain from intense exercise for 72 h prior to Visit 2 and for 72 h prior to Visit 3 until after Visit 5.
13. Agree to avoid anal penetration for 72 h prior to fecal sample collection.
14. Able to complete study diary daily as instructed between screening and baseline.
15. Willing and able to agree to the requirements and restrictions of this study, willing to give voluntary consent, able to understand and read the questionnaires, and carry out all study-related procedures

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
35 years

Upper age limit
65 years

Sex
All

Key exclusion criteria
1. Untreated lower body injury [e.g., partial anterior cruciate ligament (ACL) tear] within 6 months prior to screening and/or baseline.
2. Lactating, pregnant or planning to become pregnant during the study as confirmed at the

baseline visit (Visit 2).
3. Has a known sensitivity, intolerability, or allergy to eggs or any of the study product ingredients.
4. Diagnosis or self-report of allergic rhinitis (perennial activity or seasonal allergies during seasons that will overlap with the period of the conduct of the study).
5. Currently has COVID-19 or tests positive for COVID-19 within 28 days prior to baseline visit, or currently has any post COVID-19 condition(s) as defined by World Health Organization (WHO) (i. e., individuals with a history of probable or confirmed SARS-CoV-2 infection, usually three months from the onset of COVID-19 with symptoms that last for at least two months and cannot be explained by an alternative diagnosis).
6. Has received a Human Papillomavirus (HPV) or Hepatitis (A and/or B) vaccination within 4 weeks of the baseline visit (Visit 2) or any other vaccination within 2 weeks of the baseline visit (Visit 2) or plans to receive any vaccination during the period of the conduct of the study.
7. Current diagnosis or presence of lung disease [e.g., chronic obstructive pulmonary disease (COPD), pneumonia, asthma, etc.].
8. Current diagnosis or history of irritable bowel syndrome (IBS), inflammatory bowel disease (IBD, including ulcerative colitis and Crohn's disease), functional constipation or diarrhea (defined by the Rome IV diagnostic criteria), celiac disease, lactose intolerance and/or malabsorption, gastroparesis, endometriosis, diverticulosis, gastric or duodenal ulcers, pancreatitis, or eating disorder, history of intestinal surgery (excluding appendectomy or herniorrhaphy), or history of bariatric surgery.
9. Has an abnormality or obstruction of the gastrointestinal tract precluding swallowing (e.g., dysphagia) and digestion (e.g., known intestinal malabsorption, celiac disease, inflammatory bowel disease, chronic pancreatitis, steatorrhea).
10. Has been diagnosed with gastroenteritis and/or has had acute GI illness such as nausea /vomiting or diarrhea within the 4 weeks prior to the baseline visit (Visit 2).
11. History or current diagnosis of arrhythmia.
12. High blood pressure (≥140 systolic or ≥90 diastolic mmHg) as assessed at the screening and baseline visits.
13. Major surgery in three months prior to screening or planned major surgery during the course of the study.
14. Have been hospitalized in the last 12 months for psychiatric disorders (e.g., depression, bipolar disorder, schizophrenia etc.).
15. History of heart disease, renal or hepatic impairment/disease, uncontrolled diabetes (Type I or Type II), hepatic or renal dysfunction, unstable thyroid disease, immune disorders and/or immunocompromised (e.g., HIV/AIDS), cancer (except localized skin cancer without metastases or in situ cervical cancer) within five years prior to the screening visit, or any clinically significant disease or disorder which, in the opinion of the investigator, may either put the potential participant at risk because of participation in the study, or influences the results or the potential participant's ability to participate in the study.
16. History of alcohol or substance abuse in the 12 months prior to screening (including having been hospitalized for such in an in-patient or out-patient intervention program).
17. Receipt or use of TP(s) in another research study within 28 days prior to baseline or longer if the previous TP is deemed by the investigator to have lasting effects that might influence the eligibility criteria or outcomes of current study.
18. Self-report of blood donation totaling between 101 mL to 449 mL of blood within 30 days prior to screening or a blood donation of more than 450 mL within 56 days prior to baseline. Note: All volunteers will be advised not to donate blood for 30 days after completing the study.
19. Self-report of donating plasma (e.g., plasmapheresis) within 14 days prior to screening. Note: All volunteers will be advised not to donate plasma for 30 days after completing the study.
20. Any other active or unstable medical condition or use of medications/supplements/ therapies that, in the opinion of the investigator, may adversely affect the participant's ability to

complete the study or its measures or pose a significant risk to the participant

Date of first enrolment
16/12/2022

Date of final enrolment
22/04/2023

Locations

Countries of recruitment
Canada

Study participating centre
Nutrasource Pharmaceutical and Nutraceutical
203-101 Research Lane
Guelph
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Sponsor information

Organisation
IGY Immune Technologies & Life Sciences, Inc.

Funder(s)

Funder type
Industry

Funder Name
IGY Immune Technologies & Life Sciences, Inc.

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. This is an exploratory study being executed by an independent company and the results at this time are reserved as Intellectual Property for product development.

IPD sharing plan summary

Not expected to be made available