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A study to evaluate the effect of Astrobiome® supplementation in inflammation and insulin resistance in type 2 diabetes

Submission date
25/06/2023

Recruitment status
No longer recruiting

Registration date
07/07/2023

Overall study status
Completed

Last Edited
04/07/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
This study is designed to evaluate the efficacy of a postbiotic metabolite complex developed by Innovation Labo, Tokyo. The unique Japanese fermentation technology used in the production of the test product, Astrobiome, resulted in the production of more than 300 highly bioactive metabolite complexes. Unlike probiotics and prebiotics which offer only transient results and single-ingredient dietary supplements that fail to replicate the real gut microbial action, this metabolite complex developed by Innovation Labo provides a 3600 solution by directly tackling the multifaceted origin of chronic inflammation through Microbiota modulation and epigenetic expressions. Given the unique composition of hundreds of metabolites that can modulate the gut microbiome composition and promote gene expressions associated with chronic inflammation, it is hypothesized that this post-biotic nutritional supplement could reduce insulin resistance and inflammatory status. To evaluate this, parameters such as insulinemia, glycemia, insulin resistance index, inflammatory biomarkers, endotoxemia, non-esterified fatty acids (NEFA) and short-chain fatty acids (SCFA) are tested.

Who can participate?
Non-smoker adult subjects aged between 25 to 60 years (inclusive) old who have type 2 diabetes

What does the study involve?
Participants will be randomly assigned to a once-daily Astrobiome supplement or a placebo /dummy supplement for 4 weeks.

What are the possible benefits and risks of participating:
Possible benefits are a reduction in inflammation and the modulation of blood sugar. No risk is expected.

Where is the study run from?
INNOVATION LABO Sciences Co., Ltd (Japan)

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

Who is funding the study?
INNOVATION LABO Sciences Co., Ltd (Japan)

Who is the main contact?
Dr Yuki Ikeda, development@innovationlabo.com (Japan)

Contact information

Type(s)
Scientific

Contact name
Dr Yuki Ikeda

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IL/NG 21-1228

Study information

Scientific Title
Double-blind placebo controlled clinical study to evaluate the effect of supplementation with Astrobiome during 4 weeks in insulin resistance and inflammation in Type 2 diabetic patients

Study objectives

Astrobiome is more efficient than a placebo at decreasing inflammation and improving insulin resistance in type 2 diabetic patients

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/11/2022, Japanese Society of Anti-Aging Nutrition (Ginza, Chuo-ku, Tokyo 6-6-1, Tokyo, 104-0061, Japan; +81 3 3552 5277; coordinator@jaan.jp), ref: ILOS20827-N129

Study design
Interventional double-blind placebo-controlled single-center randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Laboratory

Study type(s)
Quality of life, Treatment, Efficacy

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

Health condition(s) or problem(s) studied
Prevention of inflammation in patients with diabetes

Interventions
This study investigates 4 weeks of daily supplementation with Astrobiome (3g stick) or a placebo (dextrin 3g stick) to take in the morning before breakfast by oral administration. Block randomization was used to allocate participants to each group. Products are to take directly in the mouth with a glass of water.

Block randomization is used to divide potential patients into m blocks of size 2n, randomize each block such that n patients are allocated to A and n to B then choose the blocks randomly. This method ensures equal treatment allocation within each block if the complete block is used.

Intervention Type
Supplement

Primary outcome measure
The following primary outcome measures are assessed at baseline and 4 weeks:
1. Fasting plasma insulin measured by radioimmunoassay
2. HbA1C measured using a latex agglutination immunoassay
Homeostatic model assessment (HOMA) is calculated as Insulinemia *Glycemia/22.5= Insulin Resistance index

Secondary outcome measures
The following secondary outcome measures are assessed at baseline and 4 weeks:
1. IL-6 measured using enzyme-linked immunosorbent assay
2. TNF-a measured using enzyme-linked immunosorbent assay
3. Serum endotoxin level measured by immunoassay
4. Serum and Fecal Short Chain fatty acids measured using Gas Chromatography-Mass spectrometry (GC-MS)
5. Spontaneously reported and observed adverse events after the first dose until the end of the treatment visit

Overall study start date
01/02/2022

Completion date
08/06/2023

Eligibility

Key inclusion criteria
1. Non-smoker female and male subjects between 25 to 60 years (inclusive) of age with Type 2 diabetes (FPG (≥ 126.0 mg/dl or 7.0mmol/L) for more than 6 months
2. Subjects with a BMI range of 25-35 kg/m2 (both inclusive)
3. Subjects using any medicines for diabetes must be stable on those medicines for a minimum of 3 months
4. Subject agreeing not to start any new anti-diabetic medicines or supplements during the course of the study
5. Females of child-bearing potential must agree to use an approved form of birth control and to have a negative pregnancy test result at the screening visit.
Female subjects of non-childbearing potential must be amenorrheic for at least 1 year or had a hysterectomy and/or bilateral oophorectomy.
6. Willing to give written informed consent and willing to comply with the trial protocol
7. Ability to understand the risks/benefits of the protocol
8. Subject should be available for the duration of the study period (1 month)

Participant type(s)
Patient

Age group
Adult

Lower age limit
25 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
50

Total final enrolment
50

Key exclusion criteria
1. Subjects suffering from gastrointestinal, CVD, renal, thyroid, liver or pancreatic diseases.
2. Subjects taking vitamins, prebiotics or probiotics.
3. Subjects having liver diseases.
4. Subjects on prolonged (Greater than 6 weeks) medication with corticosteroids, antidepressants, anticholinergics, antipsychotic drugs, etc. or any other drugs that may have an influence on the outcome of the study.
5. Subjects with a history of alcohol or drug abuse
6. Pregnant/lactating woman
7. Subjects using other modulators like diet control, yoga, herbal supplements, etc and wish to continue after enrolment.

Date of first enrolment
20/02/2023

Date of final enrolment
30/03/2023

Locations

Countries of recruitment
Japan

Study participating centre
Medica Tokyo Laboratories
14-5 Kusunokichō, Nishi-ku
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Sponsor information

Organisation
INNOVATION LABO Sciences Co., Ltd

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Sponsor type
Industry

Website
http://www.innovationlabo.com

Funder(s)

Funder type
Industry

Funder Name
INNOVATION LABO Sciences Co., Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/09/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Yuki Ikeda, development@innovationlabo.com. Anonymised IPD will be available upon publication of results and for a period of 2 years. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request