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Clinical study to evaluate the efficacy of probiotics in reducing weight in Asian subjects

Submission date
12/02/2025

Recruitment status
No longer recruiting

Registration date
13/02/2025

Overall study status
Completed

Last Edited
12/02/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
Obesity is a complex condition that goes beyond just excess weight; it is linked to various health problems and is becoming a growing global issue. These related conditions include type 2 diabetes, high blood pressure, breathing difficulties, joint problems, circulation disorders, and even depression. All of these can seriously affect overall health and increase the risk of illness and death.
Research has shown that an imbalance in gut bacteria (microbiota) can negatively impact weight control, energy balance, and how the body processes fats and sugars.
In recent decades, obesity rates among Chinese adults have risen significantly. Synbalance S.r.l., the sponsor of this study, aims to evaluate whether a food supplement can help overweight or obese Asian individuals lose weight. The study will also assess whether the supplement can improve quality of life and positively affect cholesterol, triglycerides, glycemia, insulin levels, fat distribution, diabetes-related indices, and its action on the fecal microbiome.
A randomized, double-blind, placebo (dummy) -controlled trial with 66 healthy overweight/mild obese male and female participants with large waist will assess the efficacy of the food supplement contaiing probiotics, compared to placebo. Participants will take the supplement daily, with evaluations at baseline, 56, and 84 days, alongside adverse event monitoring.

Who can participate?
Healthy male and female subjects aged between 18 and 45 years, overweight/mild obese and with large waist.

What does the study involve?
Participants will be asked to attend clinic visits at screening, at baseline and after 56 and 84 days of treatment.
During the screening visit, the medical doctor will inform the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent will be enrolled in the study.
All the measurements/assessments performed during the visits will be carried out using minimally invasive procedures and blood samples will be taken by a professional nurse.

What are the possible benefits and risks of participating?
Risks associated with the product intake are considered from low to very low, in absence of allergy/intolerances to product ingredients; other ingredients in the product formula are commonly used in dietary supplements.
The potential benefits associated with the use of the product are related to a reduction of body weight and an improvement in quality of life of overweight/mild obese subjects.

Where is the study run from?
Complife Beijing Testing Technology Co., Ltd, China

When is the study starting and how long is it expected to run for?
July 2024 to July 2025

Who is funding the study?
SynBalance Srl (Italy)

Who is the main contact?
Roberta Villa, roberta.villa@complifegroup.com

Contact information

Type(s)
Public, Scientific

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Type(s)
Principal investigator

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
PROBESI 2025

Study information

Scientific Title
Clinical evaluation of the weight loss efficacy of a food supplement: a randomized double-blind placebo-controlled study on Asian subjects

Acronym
SLIMASIA

Study objectives
There will be a positive effect of a food supplement in reducing body weight in overweight /mildly obese Asian subjects.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/11/2024, Comitato Etico Indipendente presso la società Derming S.r.l. (Independent Ethics Committee operating at Dermings s.r.l.) (Via Morone, 6, Milano, 20121, Italy; +39 2 23183475; adele.sparavigna@derming.com), ref: V221124

Study design
Double blind randomized parallel-group placebo-controlled

Primary study design
Interventional

Study type(s)
Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Overweight/mild obese

Interventions
The product under study consists of a food supplement containing probiotics.
Half of the recruited subjects will be randomized to receive the active product and half of the recruited subjects will be randomized to receive the placebo product.
A restricted randomization list will be generated by the study director using PASS 11 software (PASS, LLC. Kaysville, UT, USA) and the appropriate randomization algorithm ("Wey's urn") and stored in a safe place.
An independent technician dispenses the products according to the randomization list.
The study will be double blind: subjects, investigator and collaborators are kept masked to products assignment.
Products will be supplied in the same packaging without any obvious differences among

products.
Subjects will take the assigned food supplement (once a day) for 84 days.

Intervention Type
Supplement

Primary outcome(s)
1. Body weight (kg) at baseline, and after 56 days and 84 days of treatment
2. Body Mass Index (kg/m²) at baseline, and after 56 days and 84 days of treatment
3. Waist circumference (cm) at baseline, and after 56 days and 84 days of treatment
4. Hip circumference (cm) at baseline, and after 56 days and 84 days of treatment

Key secondary outcome(s))
1. Obesity-related Quality of Life (ORWELL-97) at baseline, and after 56 days and 84 days of treatment
2. Blood parameters at baseline, and after 56 days and 84 days of treatment:
2.1. Total Cholesterol (mmol/l)
2.2. HDL cholesterol (mmol/l)
2.3. LDL cholesterol (mmol/l)
2.4. Triglycerides (mmol/l)
2.5. Fasting Insulin (pmoI/l)
2.6. Fasting Glucose (mmol/l)
2.7. HbA1c (mmol/l)
3. Fecal microbiome analysis at baseline, and after 84 days of treatment
4. Conicity index (CI) at baseline, and after 56 days and 84 days of treatment
5. Visceral Adiposity Index (VAI) at baseline, and after 56 days and 84 days of treatment
6. HOMA index (Homeostasis Model Assessment) at baseline, and after 56 days and 84 days of treatment
7. Self-evaluation questionnaire (polytomous question with four possible answers) after 84 days of treatment
8. Incidence and nature of Adverse Event (AE) and Serious Adverse Event (SAE) after 56 days and 84 days of treatment

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Asian ethnicity
3. Aged between 18 and 45 years (including extremes)
4. Subjects overweight/mild obese (BMI between 26 and 31.9 kg/m²)*
5. Subjects with large waist (waistline >80 centimetres for women and >85 centimetres for men)
6. Subjects certifying the truthfulness of the personal data disclosed to the investigator
7. Subjects able to understand the language used in the investigation center and the information given by the investigator
8. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
9. Commitment not to change the daily routine or the lifestyle**
10. Stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion

criteria) for at least one month without any changes expected or planned during the study
11. Subject is under effective contraception (oral/not oral) therapy if fertile
12. Subjects informed about the test procedures who have signed a consent form and privacy policy

*According to “Health standards of the People’s Republic of China”, National Health and Family Planning Commission of the People's Republic of China:
Classification BMI
Obese BMI ≥ 28.0 kg/m²
Overweight 24.0 kg/m² ≤ BMI < 28.0 kg/m²
Normal 18.5 kg/m² ≤ BMI < 24.0 kg/m²
Underweight BMI < 18.5 kg/m²
** Subjects will keep a food diary to ensure that they do not change their eating habits during the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
All

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Subjects participating or planning to participate in other clinical trials
3. Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
4. Subjects who are currently using food supplement(s) and/or topical products with the same activity as the study product, or who haven't observed an adequate washout period since stopping use (at least one month)
5. Subjects admitted to a health or social facility
6. Subjects planning a hospitalization during the study
7. Subjects not able to be contacted in case of emergency
8. Subjects deprived of freedom by administrative or legal decision or under guardianship
9. Subjects with a history of drug, alcohol, and other substance abuse
10. Alimentary/Eating disorders (i.e., bulimia, psychogenic eating disorders, etc.)
11. Smokers
12. Subject breastfeeding, pregnant, or not willing to take necessary precautions to avoid pregnancy during the study (for women of childbearing potential)
13. Subjects with any acute, chronic, or progressive disease or skin condition that may interfere

with the study data or that the investigator considers dangerous to the subject or incompatible with the requirements of the study
14. Subjects that have food intolerances or food allergies or allergy to ingredients of the study product or allergy to any of the ingredients in the product under investigation
15. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator

Date of first enrolment
14/02/2025

Date of final enrolment
28/03/2025

Locations

Countries of recruitment
China

Italy

Study participating centre
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Study participating centre
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87036

Sponsor information

Organisation
SynBalance srl

Funder(s)

Funder type

Industry

Funder Name
SynBalance srl

Results and Publications

Individual participant data (IPD) sharing plan
Raw data will be stored on the Complife Beijing Testing Technology Co. and Nutratech server. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study sponsor by a pdf file electronically signed. The raw data will be stored for a minimum period of 10 years on Complife servers. In the raw data tables, subjects are identified by a means of a code generated by the Complife volunteer’s management software. The code is composed of a letter, four digits, and a letter. Access to the study's raw data is allowed by application only to the study director and the person designated by him to elaborate on the raw data. Elaboration of the raw data includes descriptive statistics and inferential analysis.

IPD sharing plan summary
Stored in non-publicly available repository, Published as a supplement to the results publication