Study Identification

Protocol ID: Probi.Obes

Brief Title: Clinical Trial to Evaluate the Effect of a Probiotic Product on Weight

Official Title: Randomized, Double-blind, Placebo-controlled Clinical Trial to Evaluate the Efficacy of a Probiotic Product in Weight Control

Study Status

Overall Status: Recruiting

Study Start: February 2025 [Anticipated]

Primary Completion: November 2025 [Anticipated]

Study Completion: December 2025 [Anticipated]

Sponsor/Collaborators

Sponsor: Bioithas SL

Human Subjects Review – Ethics Committee

Board Status: Approved

Approval Number: CE112403

Board Name: UCAM Research Ethics Committee

Board Affiliation: Universidad Católica San Antonio de Murcia (UCAM)

Study Description

Brief Summary: The study of the intestinal microbiota and its relationship with health and disease, as well as the use of probiotics as effective alternative treatments to improve people's well-being is a field of growing research in recent years. Overweight and obesity are increasingly common due to the current lifestyle, but this is not incompatible with the growing interest of the population in taking care of themselves, both physically and psychologically, and, in general, the interest in food supplements, including those based on probiotics, is increasingly common. The objective of the clinical trial is to evaluate the effectiveness of a food supplement based on probiotics to reduce body weight in 104 volunteers with overweight and type I obesity (BMI 25 - 34.9 kg/m2). This randomized, double-blind and placebo-controlled clinical trial has a 12week intervention period, during which subjects have to take a daily dose of the product

(probiotic or placebo). In this trial, anthropometric clinical data, the effect of the intervention on blood parameters and the composition of the intestinal microbiota will be analyzed.

Conditions: Overweight, Obesity Grade I

Keywords: probiotics overweight obesity food supplement gut microbiota

Study Design

Study Type: Randomized, double-blind, placebo-controlled with parallel assignment

Number of Arms: 2

Enrollment: 104 [Anticipated]

Arms and Interventions

Experimental arm: PROBIOTIC

Food supplement based on probiotics in capsule format. Dose: 1 capsule/day. The active capsules contain probiotic strains at ≥1×10^9 cfu/dose and excipient.

Placebo comparator: PLACEBO

Food supplement in capsule format. Dose: 1 capsule/ day. The placebo capsules contain only excipients (probiotics are not included).

Outcome Measures

Primary Outcome Measure:

1. Changes in body weight between baseline and 6- and 12-weeks
2. Changes in body mass index (BMI) baseline and 6- and 12-weeks

Secondary Outcome Measure:

3. Changes in waist/hip circumference ratio between baseline and 6- and 12-weeks
4. Changes in body composition between baseline and 12-weeks
   Body composition is assessed by DEXA (Dual-Energy X-ray Absorptiometry). Lean mass and fat mass of the different body regions will be measured as grams (g) and percentage (%).
5. Changes in blood pressure between baseline and 6- and 12-weeks

6. Changes in gut microbiota composition between baseline and 12-weeks
   Alpha diversity, beta diversity and bacterial taxonomic composition of the gut microbiota will be assessed by sequencing the 16S rRNA gene of stool samples.

7. Changes in the score of gastrointestinal symptoms questionnaire between baseline and 6- and 12-weeks
   Questionnaire with 15 questions related to gastrointestinal discomfort during the last month. Each question is valued according to: None = 1; Insignificant = 2; Mild = 3; Moderate = 4; Quite strong = 5; Strong = 6; and Very strong = 7.
   The total score is calculated by adding the number of answers answered for the different degrees of discomfort (1-7), and is between 15 and 105 points. The higher the score, the worse the indication of gastrointestinal symptoms.

8. Changes in the score of International Physical Activity Questionnaire (IPAQ) between baseline and 12-weeks
   International Physical Activity Questionnaire (IPAQ) measures the time spent being physically active during the past 7 days. The type of activity is divided into: vigorous activity, moderate activity, walking, and no activity (sitting).
   Weekly activity is recorded in Mets (Metabolic Equivalent of Task or Metabolic Rate Units) per minute and week. The reference Mets values are: Walking: 3.3 Mets, Moderate physical activity: 4 Mets, Intense physical activity: 8 Mets.
   To obtain the total number of Mets, the reference Mets values are multiplied by the time in minutes of performing each type of activity in a day and by the number of days per week that it is performed. Depending on the number of Mets, physical activity is categorized as high, moderate, or low.

9. Changes in the MEDiterranean LIFEstyle index (MEDLIFE) questionnaire between baseline and 12-weeks
   The MEDiterranean LIFEstyle index (MEDLIFE) consists of 28 questions categorized into three blocks: 1. Consumption of Mediterranean foods (15 questions); 2. Mediterranean dietary habits (7 questions); and 3. Physical activity, rest, social habits and coexistence (6 questions).
   Each question is scored with 0 or 1 point depending on whether or not it meets the established criteria, so the total score is between 0 and 28 points (the higher the score, the greater the adherence to the Mediterranean lifestyle).

10. Changes in the score of the Simplified Nutritional Appetite Questionnaire (SNAQ) between baseline and 12-weeks
    Simplified Nutritional Appetite Questionnaire (SNAQ) The questionnaire consists of 4 questions. The results are scored on the following numerical scale: a 1, b 2, c 3, d 4, e 5. The sum of the scores for the individual items constitutes the SNAQ score. The total score ranges from 5 to 20 points.

11. Changes in blood parameters between baseline and 12-weeks Values of complete blood count.
    Blood values of: blood count, glucose, insulin, glycosylated hemoglobin (HbA1c), LDL and HDL, and total cholesterol, triglycerides, creatinine, urea, AST/GOT, ALT/GPT, C-reactive protein and leptin.

<u>Other Pre-specified Outcome Measures:</u>

12. Adverse events (AEs) at 6- and 12-weeks.
    AEs reported by participants, whether or not related to the intake of the investigational products, including required pharmacological treatments if applicable.

13. Adherence rate to the investigational product at 6- and 12-weeks.
    Adherence is assessed through leftover capsules and days between visits.

Eligibility

Inclusion Criteria:

- Men and women aged ≥ 18 years.
- Body Mass Index (BMI) between 25.0 and 34.9 (overweight or obesity type I).
- Commitment to maintaining a lifestyle, including diet and sports habits, constant throughout the study.
- Signing of informed consent.

Exclusion Criteria:

- Subjects with diabetes (type I or II), hypothyroidism or other diseases that may promote weight gain.
- Presence of other serious pathologies, including cancer or autoimmune diseases, or any other that, at the medical discretion of the investigator, may influence the results of the study.
- Subjects who have participated in a weight loss program or who have substantially modified their lifestyle habits (diet, physical exercise) during the previous 3 months.
- Treatment with antibiotics in the previous 4 weeks.
- Consumption of products or drugs intended for weight loss or satiety control, or that may influence weight in the previous 4 weeks.
- Consumption of products containing probiotics in the previous 2 months.
- Contraindication to taking the product under investigation, or allergy or intolerance to any of its ingredients.
- In the case of women: pregnancy or breastfeeding, or plans to become pregnant during the course of the study.

Contacts/Locations

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