

A study evaluating the efficacy of a food supplement in supporting weight loss and reducing perceived food cravings compared to a placebo

Submission date 30/04/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 25/05/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/05/2026	Condition category Other	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

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Additional identifiers

Clinical Study Protocol Number

EC_P0000902/25

Study Code_Order

H.E.HU.MP.NRM00.060.05.00_IT0008587/25

Study information

Scientific Title

Clinical evaluation of the efficacy of a food supplement on body weight and perceived food craving: a randomized, double-blind, parallel-group, placebo-controlled study

Study objectives

The primary objective is to evaluate the efficacy of the product in body weight reduction, assessed through body weight measurement and calculation of Body Mass Index (BMI). The secondary objective is to evaluate additional effects on body composition parameters (waist and hip circumference, fat mass). Additionally, the study will evaluate participants' self-perceived changes in food craving control, appetite-related sensations, body perception, overall well-being, and product acceptability through a self-assessment questionnaire.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 07/04/2026, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (Milano), Milano, 20045, Italy; +39 3783037302; secretariat@ieiccommittee.com), ref: IC0019 A

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Blinded (masking used)

Control

Placebo

Assignment

Parallel

Purpose

Treatment, Efficacy

Study type(s)

Health condition(s) or problem(s) studied

Excessive food cravings

Interventions

The investigational product is SelectSIEVE®LIBRA, containing 60% Salvia officinalis extract and 40% Morus alba (white mulberry) extract, with maltodextrin and magnesium stearate as excipients.

The placebo contains maltodextrin and magnesium stearate only.

Half of the recruited subjects are randomized to receive the active product, while the other half receive the placebo. A restricted randomization list is generated by an independent technician using the appropriate algorithm (Wey's urn) implemented in PASS 11 software (PASS, LLC, Kaysville, UT, USA) and stored in a secure location. The principal investigator or a designated delegate dispenses the investigational products according to the randomization list.

The study is conducted as a double-blind trial: subjects, investigators, and collaborators are blinded to product allocation. Both the active and placebo products are provided in identical packaging, with no distinguishable differences between them.

The study is structured into two phases: a one-month screening period prior to product intake, followed by 84 days of treatment. Clinical visits are scheduled at T-28 (initial visit), T0 (baseline visit), and follow-up visits at T14, T28, T56, and T84 (final visit).

Subjects take the assigned treatment for 84 ± 2 days as follows: 2 capsule per day, half an hour before dinner, with a glass of water.

Intervention Type

Supplement

Primary outcome(s)

1. Body weight (Kg) measured using a scale at T0, T14, T28, T56, T84

2. Body Mass Index (BMI) (kg/m^2) measured using weight (kg) / height² (m^2) at T0, T14, T28, T56, T84

Key secondary outcome(s)

1. Waist circumference (cm) measured using a tape at T0, T14, T28, T56, T84
2. Hip circumference (cm) measured using a tape at T0, T14, T28, T56, T84
3. Fat Mass (FM) (kg) measured using the BIA 101 ASE device (Bioelectrical Impedance Analysis) at T0, T14, T28, T56, T84
4. Self-evaluation questionnaire measured using 17 multiple-choice questions assessing perceived efficacy and product pleasantness at T14, T28, T56, T84

Completion date

04/09/2026

Eligibility

Key inclusion criteria

1. Healthy male and female subjects
 2. 90% Caucasian subjects; 10% mixed-ethnicity subjects
 3. Subjects aged between 18 and 45 years (extremes included)
 4. Subjects who are overweight at screening (at the recruitment, BMI between 25 kg/m² and 29.9 kg/m², according to the World Health Organization (WHO) BMI Classification)
 5. Subjects with stable body weight at screening, defined as a fluctuation of no more than ± 2 kg during the one-month screening phase, with body weight assessed every 14 days
 6. Subjects with a stable, light-to-moderate physical activity level (e.g., routine daily mobility such as walking ≥ 30 minutes/day or equivalent), not engaged in competitive sports or structured training programs that may significantly influence body weight or body composition, and willing to maintain their habitual activity level throughout the entire study duration
 7. Subjects who commit not to change their daily routine throughout the entire study period (screening and experimental phases)*
 8. Subjects with self-perceived excessive food craving at screening, defined as a score ≥ 6 on a 0–10 Visual Numeric Scale (VNS).
 9. Subjects registered with the national public health system in the country where the study is conducted
 10. Subjects certifying the truthfulness of the personal data disclosed to the investigator
 11. Subjects able to understand the language used in the investigation centre and the information given by the investigator
 12. Subjects able to respect the instructions given by the investigator as well as able to respect the study constraints and specific requirements
 13. Subjects on 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
 14. Subjects informed about the test procedures who have signed a consent form and privacy agreement
- * Subjects will complete a daily food and physical activities diary to monitor their habitual diet and quotidian/physical activity. Diaries will be collected during the one-month screening period and at each month of treatment (T28, T56, and T84).

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

All

Total final enrolment

66

Key exclusion criteria

1. Subjects who do not meet the inclusion criteria
2. Menopausal or perimenopausal subjects
3. Subjects with any acute, chronic, or progressive disease or 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**
4. Subjects currently following a weight-loss diet/program or who started a structured diet /exercise program within the last 3 month
5. Subjects participating or planning to participate in other clinical trials
6. Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
7. Subjects that have food intolerances or food allergies to ingredients of the study product
8. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator ***
9. Subjects who are currently using food supplement(s) and/or products with the same activity as the study product, or who haven't observed an adequate washout period (at least one month)
10. Subjects admitted to a health or social facility
11. Subjects planning a hospitalization during the study
12. Subjects not able to be contacted in case of emergency
13. Subjects deprived of freedom by administrative or legal decision or under guardianship
14. Subjects who have or have had a history of alcohol or drug addiction
15. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
16. Subjects breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)

** Including malignancy, severe cardiovascular disease, severe hepatic or renal impairment, neurological or psychiatric disorders, serious infections, autoimmune diseases or any medical condition that may affect body weight, appetite, or eating behavior or any condition considered by the Principal Investigator to interfere with the study.

*** Including the use of medications known to affect body weight, appetite, or eating behavior or any medication considered by the Principal Investigator to interfere with the study.

Date of first enrolment

07/04/2026

Date of final enrolment

22/04/2026

Locations

Countries of recruitment

Italy

Romania

Sponsor information

Organisation

ROELMI HPC S.R.L., Via Celeste Milani 24/26 – 21040 Origgio (VA), Italy

Funder(s)

Funder type

Funder Name

ROELMI HPC. S.R.L.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			01/05/2026	No	No