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Evaluation of the efficacy of a food supplement for subjects with metabolic syndrome

Submission date 03/02/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [X] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/02/2026	**Overall study status** Completed	
Last Edited 17/06/2026	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

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Clinical Study Protocol Number
EC_NT0000414/25

Study Code_Order
H.E.HU.HV.NMS00.060.03.00_NT0001644-25

Study information

Scientific Title
Clinical evaluation of the efficacy of a food supplement for subjects with metabolic syndrome: a randomized, double-blind, parallel-group, placebo-controlled study

Study objectives
The primary objective of this study is to evaluate the efficacy of the product in improving selected parameters related to metabolic syndrome. The secondary objective of this study is to evaluate the efficacy of the product in improving selected metabolic indices and inflammatory status to metabolic syndrome.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 28/01/2026, International Ethics and Integrity Committee (Via Per Garbagnate 61, Lainate (MI), Lainate, 20045, Italy; +39 3783037302; secretariat@ieicomittee.com), ref: Rif. IC0014 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
Healthy subjects with overweight or mild obesity and with metabolic syndrome.

Interventions
The active product is a food supplement containing Hops extract (Humulus Lupulus L.), while the placebo contains the same excipients without the active ingredients.
A restricted randomization list will be generated by an independent technician using the appropriate algorithm ("Wei'surn") of the PASS 11 software (PASS, LLC. Kaysville, UT, USA) and stored in a secure location. The Principal Investigator or designated personnel will dispense the products according to the generated randomization list: half of the subjects will be allocated to the active product and half of the subjects will be allocated to a placebo.
The study will be double-blind, meaning that subjects, Principal Investigator and collaborators are kept masked to products assignment. The products will be supplied in the same packaging with no obvious differences between them.
Subjects will take the assigned treatment for 84 days ± 2 days as follows: one capsule per day, in the morning, on an empty stomach, with a glass of water.

Intervention Type
Supplement

Primary outcome(s)
1. Waist circumference measured using a tape (cm) at baseline, 56 and 84 days

2. Body weight measured using a scale (kg) at baseline, 56 and 84 days

3. Body Mass Index (BMI) measured using the formula: BMI = weight / height^2 at baseline, 56 and 84 days

4. Total cholesterol (TC) measured using blood analysis (mg/dl) at baseline, 56 and 84 days

5. High-density lipoprotein cholesterol (HDL-C) measured using blood analysis (mg/dl) at baseline, 56 and 84 days

6. Low-density lipoprotein cholesterol (LDL-C) measured using blood analysis (mg/dl) at baseline, 56 and 84 days

7. Triglycerides (TG) measured using blood analysis (mg/dl) at baseline, 56 and 84 days

8. Fasting glucose (FG) measured using blood analysis (mg/dl) at baseline, 56 and 84 days

9. Fasting Insulin (FI) measured using blood analysis (µU/ml) at baseline, 56 and 84 days

10. Glycated hemoglobin (HbA1c) measured using blood analysis (% or mmol/l) at baseline and 84 days

Previous primary outcome(s):

1. Waist circumference measured using a tape (cm) at baseline, 56 and 84 days.
2. Body weight measured using a scale (kg) at baseline, 56 and 84 days.
3. Body Mass Index (BMI) measured using the formula: BMI = weight / height^2 at baseline, 56 and 84 days.
4. Total cholesterol (TC) measured using blood analysis (mg/dl) at baseline, 56 and 84 days.
5. High-density lipoprotein cholesterol (HDL-C) measured using blood analysis (mg/dl) at baseline, 56 and 84 days.
6. Low-density lipoprotein cholesterol (LDL-C) measured using blood analysis (mg/dl) at baseline, 56 and 84 days.
7. Triglycerides (TG) measured using blood analysis (mg/dl) at baseline, 56 and 84 days.
8. Fasting glucose (FG) measured using blood analysis (mg/dl) at baseline, 56 and 84 days.
9. Fasting Insulin (FI) measured using blood analysis (µU/ml) at baseline, 56 and 84 days.
10. Glycated hemoglobin (HbA1c) measured using blood analysis (% or mmol/l) at baseline, 56 and 84 days.

Key secondary outcome(s)
1. HOMA-IR (Homeostasis Model Assessment of Insulin Resistance) measured using a specific mathematical formula at baseline, 56 and 84 days.

2. Visceral Adiposity Index (VAI) measured using a specific mathematical formula at baseline, 56 and 84 days.

3. High-sensitivity C-Reactive Protein (hs-CRP) measured using blood analysis at baseline, 56 and 84 days.

Completion date
29/05/2026

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Subjects of Caucasian ethnicity
3. Subjects aged between 18 and 64 years (extremes included)
4. Subjects with overweight or mild obesity *
5. Subjects with metabolic syndrome**
6. Subjects registered with national health service
7. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated Personnel
8. Subjects able to understand the language used in the investigation center and the information given by the Principal Investigator or designated personnel
9. Subjects able to respect the instructions given by the Principal Investigator or designated

personnel as well as able to respect the study constraints and specific requirements
10. Subjects who commit not to change their daily routine or lifestyle during the study***
11. 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
12. Subjects informed about the test procedures who have signed a consent form and privacy agreement.
* At the recruitment, BMI between 25 kg/m² and 34.9 kg/m² (overweight and obesity class I). According to the World Health Organization (WHO) BMI Classification
** According to the International Diabetes Federation (IDF). At least three out of five required:
1. Large waist circumference (≥ 94 cm for males and ≥ 80 cm for females)
2. Low HDL cholesterol levels (<40 mg/dl for males and <50 mg/dl for females)
3. High triglyceride levels (≥ 150 mg/dl)
4. High fasting glucose levels (≥ 100 mg/dl)
5. High blood pressure (≥ 130/85 mmHg)
*** Subjects will maintain a weekly diary to record their dietary habits and physical activity

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
All

Total final enrolment
66

Key exclusion criteria
1. Subjects who do not meet the inclusion criteria
2. Female subjects who consume ≥ 140 g/week of alcohol and male subjects who consume ≥ 210 g/week of alcohol****
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 participating or planning to participate in other clinical trials
5. Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
6. Subjects that have food intolerances or food allergies to ingredients of the study product
7. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the investigator ******
8. 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)
9. Subjects admitted to a health or social facility

10. Subjects planning a hospitalization during the study
11. Subjects not able to be contacted in case of emergency
12. Subjects deprived of freedom by administrative or legal decision or under guardianship
13. Subjects who have or have had a history of alcohol or drug addiction
14. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
15. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential)
**** According to the American Association for the Study of Liver Diseases guidelines for nonalcoholic fatty liver disease
***** Including severe hepatic or kidney disease, serious infections, and malignancies
****** Including medications to manage blood glucose levels (e.g., metformin, sulfonylureas, DPP-4 Inhibitors, GLP-1 Agonists), lipid disorders (e.g., statins, fibrates, niacin), high blood pressure (e.g., ACE Inhibitors, Angiotensin II Receptor Blockers, Beta-Blockers, Calcium Channel Blockers), as well as treatments for weight control and any food supplements intended for metabolic syndrome (MetS). Corticosteroids, antidepressants, antipsychotics

Date of first enrolment
28/01/2026

Date of final enrolment
09/02/2026

Locations

Countries of recruitment
Italy

Study participating centre
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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	version 01	16/12/2025	17/06/2026	No	No
Statistical Analysis Plan	version 01	16/12/2025	17/06/2026	No	No