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

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2026	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/01/2026	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/03/2026	Nutritional, Metabolic, Endocrine	[X] Record updated in last year

Plain English summary of protocol
Plain English summary of protocol not provided at time of registration

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Clinical Study Protocol
EC_NT0000405/25

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 verify the tolerability of the product.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/12/2025, International Ethics and Integrity Commitee (Via Per Garbagnate 61, Lainate (MI), Lainate, 20045, Italy; +39 3783037302; secretariat@ieicomittee.com), ref: IC008 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 volunteers with metabolic syndrome and overweight

Interventions
The active intervention is a food supplement containing the extract of Cynara cardunculus L. var. altilis DC. and scolymus (Altilix), while the placebo intervention contains the same excipients

without the active extract.
A restricted randomization list will be generated by an independent technician using the appropriate algorithm ("Wei’s urn") 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 randomization list generated.
The study will be double-blind, meaning that subjects, Principal Investigator and collaborators are kept masked to products assignment. Both the active and placebo will be supplied in the same packaging with no obvious differences between them. Subjects take the assigned treatment for 140 ± 2 days as follows: one capsule per day intake after breakfast with water.

Intervention Type
Supplement

Primary outcome(s)
1. Lipid metabolism measured using a blood analysis for the total cholesterol (TC) (mg/dL), high-density lipoprotein cholesterol (HDL-C) (mg/dL), low-density lipoprotein cholesterol (LDL-C) (mg /dL), triglycerides (TG) (mg/dL) at baseline and after 56 and 140 days

2. Liver function measured using a blood analysis for the Alanine Aminotransferase (ALT) (U/L), Aspartate Aminotransferase (AST) (U/L), AST/ALT ratio , Gamma-Glutamyl Transferase (GGT) (U /L), fatty Liver Index (FLI) at baseline and after 56 and 140 days

3. Carbohydrate metabolism measured using a blood analysis for the fasting glucose (FG) (mg /dL), fasting Insulin (FI) (µU/ml), glycated hemoglobin (HbA1c) (% and mmol/mol), homeostasis model assessment of insulin resistance (HOMA-IR), homeostasis model assessment of beta, cell function (HOMA-B%) at baseline and after 56 and 140 days

4. Anthropometric parameters and blood pressure measured using a tape for the waist circumference (WC) (cm), a scale for the body weight (BW) (kg), Body Mass Index (BMI) (kg/m2) , visceral Adiposity Index (VAI), an automatic device on seated subjects for the systolic blood pressure (mmHg) and diastolic blood pressure (mmHg) at baseline and after 56 and 140 days

5. Antioxidant effect measured using a capillary blood for the marker of oxidative stress: d-ROMs (derivatives-Reactive Oxygen Metabolites) concentration (Carratelli units) at baseline and after 56 and 140 days

Key secondary outcome(s)
1. Renal tolerability measured using a blood analysis for creatinine (mg/dL) at baseline and after 56 and 140 days

2. Inflammatory status monitoring measured using a blood analysis for hs-C-Reactive Protein (hs-CRP) (mg/dL) at baseline and after 56 and 140 days

3. Hematological monitoring measured using a blood analysis for complete blood count (CBC): red blood cells (106/µL), leukocyte Count (103/µL) , hemoglobin (g/dL) , hematocrit (%) , platelets (103/µL) at baseline and after 56 and 140 days

Completion date
04/12/2026

Eligibility

Key inclusion criteria
1. Healthy male and female subjects
2. Subjects of Caucasian ethnicity
3. Subjects aged between 35 and 55 years (extremes included)
4. Subjects with metabolic syndrome *
5. Subjects who are overweight **
6. Subjects registered with National Health Service (NHS)
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 centre 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
* According to the International Diabetes Federation (IDF). At least three out of five required:
- Large waist circumference (≥ 94 cm for males and ≥ 80 cm for females)
- Low HDL cholesterol levels (<40 mg/dl for males and <50 mg/dL for females)
- High triglyceride levels (≥ 150 mg/dL)
- High fasting glucose levels (≥ 100 mg/dL)
- High blood pressure (≥ 130/85 mmHg)

** BMI between 25 kg/m2 and 29.9 kg/m2 according to the World Health Organization (WHO) BMI Classification
*** Subjects will keep a diary to ensure that they do not change their eating or physical activity habits during the study

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
35 Years

Upper age limit
55 Years

Sex
All

Total final enrolment
0

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**** according to the American Association for the Study of Liver Diseases guidelines for nonalcoholic fatty liver disease
3. Subjects with any acute, chronic, or progressive disease or condition that may interfere with the study data or that the Principal 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 Principal 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
15/12/2025

Date of final enrolment
29/05/2026

Locations

Countries of recruitment
Italy

Study participating centre
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Sponsor information

Organisation
BIONAP S.r.l

Funder(s)

Funder type

Funder Name
BIONAP S.r.l

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available