CLINICAL STUDY PROTOCOL

STUDY TITLE

CLINICAL EVALUATION OF THE EFFICACY OF A FOOD SUPPLEMENT FOR SUBJECTS WITH METABOLIC SYNDROME: A RANDOMIZED, DOUBLE-BLIND, PARALLEL-GROUP, PLACEBO-CONTROLLED STUDY

PROTOCOL REFERENCES

Clinical Study Protocol Number:
EC_NT0000414/25

Clinical Study Protocol Version and Date of issue:
01, 16/12/2025

Concept Protocol:
NT0000414/25, 21/11/2025

Study Code_Order:
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GENERAL INFORMATION

SPONSOR

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

Authorized Signatory:
Carolina Galli, R&D Specialist

INVESTIGATORS AND SITES

Principal Investigator:
Dr. Achiropita Curti, Clinical Nutritionist

Co-investigators:
Dr. Erminia D'Ambrosio, In Vivo Safety and Efficacy Technician

SITES

Study sites:
Nutratech S.r.l. via Francesco Todaro 20/22 – 87036 Rende (CS), Italy

Other laboratories:
NUOVA GAMMA S.r.l., Viale della Repubblica 77 - 87100, Cosenza (CS), Italy

MANAGEMENT

Responsible Person:
Dr. Eleonora Spartà for Dr. Roberta Villa, Project Manager

Facility Name and address:
Complife Italia S.r.l.; office in Viale Indipendenza, 11 - 27100 Pavia (PV), Italy
Headquarters: Via Guido Rossa, 1 - 20024 Garbagnate Milanese (MI), Italy

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PROTOCOL APPROVAL

The undersigned acknowledge having read and understood the Clinical Study Protocol EC_NT0000414/25 Ver. 01, 16/12/2025. They hereby agree to its content and commit to conduct or oversee the study in full compliance with this Protocol, the Declaration of Helsinki, Good Clinical Practice (GCP), and applicable regulatory requirements.

AUTHORIZED SIGNATORY OF THE SPONSOR
Date and Signature:

Paola Galli 22/12/25

PRINCIPAL INVESTIGATOR
Date and Signature:

Adriana Carè
18.12.2025

RESPONSIBLE FOR STUDY MANAGEMENT
Date and Signature:

Eleonora Spartà

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PROTOCOL AMENDMENTS

All protocol amendments must be jointly approved and signed by the Sponsor, the Principal Investigator, and the Project Manager of the study.
Deviations during the study will be reviewed to determine whether they require a formal amendment or justify study termination.
Updates to the list of investigators and study sites will not be formally updated through protocol amendments but will be managed by the project manager (or delegate) and included in the final report.

AMENDMENTS HISTORY

Clinical Study Protocol Version and Date of issue:
00, 26/11/2025
Description:
First release

Clinical Study Protocol Version and Date of issue:
01, 16/12/2025
Description:
Minor changes

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SUMMARY

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1. PROTOCOL SUMMARY

The aim of this study is to evaluate the efficacy of a food supplement in improving selected parameters related to metabolic syndrome.

To reach this goal, a randomized, double-blind, parallel-group, placebo-controlled clinical study is planned to be performed on 66 healthy subjects with overweight or mild obesity and with metabolic syndrome, under the supervision of a board-certified clinical nutritionist. 33 subjects will assume the active product and 33 subjects the placebo for 84 days according to the instruction for use. Specific assessments will be carried out before and after 56 and 84 days of product intake. The occurrence of adverse events will be also recorded.

2. BACKGROUND AND RATIONALE

The investigational analyte consists of two components derived from a supercritical CO_2 extract of hop cones. The first component is a resin fraction obtained through supercritical CO_2 extraction, subsequently emulsified with hydrolyzed pea proteins and wheat germ oil, and converted into a powder by spray drying using gum arabic as a carrier. This powder preserves the key characteristics of the original phytocomplex: its primary bioactive constituents are bitter acids (humulones and lupulones), along with additional molecules such as xanthohumol and β-caryophyllene. The resin represents 26% of the final powdered material. The second component is an aqueous solution of iso-α-acids produced by isomerizing the humulones present in the original extract through aqueous-phase heating. This solution is then spray-dried using maltodextrin as a carrier, yielding a powder with a 50% content of iso-α-acids. The investigational ingredient administered in this study is a 1:1 mixture of these two components. [1]

The therapeutic target of the ingredient is metabolic syndrome (MetS). MetS is a multifactorial clinical condition defined by the coexistence of several cardiovascular and metabolic risk factors that act synergistically to markedly increase the probability of developing type 2 diabetes, atherosclerotic cardiovascular disease, and other long-term complications. Metabolic syndrome reflects a state of profound metabolic dysregulation, typically driven by excess visceral adiposity, insulin resistance, and low-grade chronic inflammation. According to international diagnostic criteria, the presence of at least three of the following alterations confirms the diagnosis: abdominal obesity, assessed primarily through waist circumference as an indicator of visceral fat burden; arterial hypertension, often associated with endothelial dysfunction and increased vascular stiffness; elevated fasting plasma glucose, reflecting impaired insulin action; hypertriglyceridaemia, linked to abnormal hepatic lipid metabolism; and reduced HDL-cholesterol levels, which indicate compromised reverse cholesterol transport. Together, these abnormalities contribute to an unfavourable cardiometabolic profile, increased oxidative stress, and a heightened risk of progression to overt diabetes and cardiovascular events. [2-6]

Preclinical and clinical evidence supports the biological relevance of the ingredient's components in modulating pathways associated with these risk factors. Bitter acids (α- and β-acids) activate TAS2R receptors in the intestinal epithelium, promoting the release of gut hormones such as GLP-1, CCK, and PYY. These hormones play key roles in metabolic regulation: GLP-1 enhances glucose-dependent insulin secretion, inhibits glucagon, slows gastric emptying, and increases satiety; CCK stimulates pancreatic enzyme and bile secretion and contributes to satiety; PYY reduces appetite and intestinal motility, supporting long-term appetite regulation. [7,8]

Iso-α-acids act as agonists of PPAR-α and PPAR-γ receptors, influencing lipid metabolism, adipocyte function, and insulin sensitivity. Activation of PPAR-α promotes fatty acid oxidation, reduces triglyceride levels, and increases HDL cholesterol, while PPAR-γ activation regulates adipocyte differentiation and improves insulin responsiveness. [9,10]

Additionally, β-caryophyllene has been shown to reduce metabolic inflammation by activating the CB2 receptor and modulating the endocannabinoid system.[11]

Together, these mechanisms provide a strong biological rationale for investigating the ingredient's potential benefits in individuals with metabolic syndrome.

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8. *Lela L, Carlucci V, Kioussi C, Choi J, Stevens JF, Milella L, Russo D. Humulus lupulus L.: Evaluation of Phytochemical Profile and Activation of Bitter Taste Receptors to Regulate Appetite and Satiety in Intestinal Secretin Tumor Cell Line (STC-1 Cells). Mol Nutr Food Res. 2024 Nov;68(21):e2400559. doi: 10.1002/mnfr.202400559. Epub 2024 Oct 10. PMID: 39388530.*
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10. *Yajima H, Ikeshima E, Shiraki M, Kanaya T, Fujiwara D, Odai H, Tsuboyama-Kasaoka N, Ezaki O, Oikawa S, Kondo K. Isohumulones, bitter acids derived from hops, activate both peroxisome proliferator-activated receptor alpha and gamma and reduce insulin resistance. J Biol Chem. 2004 Aug 6;279(32):33456-62. doi: 10.1074/jbc.M403456200. Epub 2004 Jun 3. PMID: 15178687.*
11. *Scandiffio R, Geddo F, Cottone E, Querio G, Antoniotti S, Gallo MP, Maffei ME, Bovolin P. Protective Effects of (E)-β-Caryophyllene (BCP) in Chronic Inflammation. Nutrients. 2020 Oct 26;12(11):3273. doi: 10.3390/nu12113273. PMID: 33114564; PMCID: PMC7692661.*

3. OBJECTIVES

3.1. Primary objective

The primary objective of this study is to evaluate the efficacy of the product in improving selected parameters related to metabolic syndrome.

Primary end-points to evaluate the effect on anthropometric parameters:

- Waist circumference (WC) (cm)
- Body weight (BW) (kg)
- Body Mass Index (BMI) (kg/m^2)

Primary end-points to evaluate the effect on lipid metabolism:

- 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)

Primary end-points to evaluate the effect on carbohydrate metabolism:

- Fasting glucose (FG) (mg/dL)
- Fasting Insulin (FI) (µU/ml)
- Glycated haemoglobin (HbA1c) (mmol/mol or %)

3.2. Secondary objectives

The secondary objective of this study is to evaluate the efficacy of the product in improving selected metabolic indices and inflammatory status.

Secondary end-point to evaluate the effect on metabolic indices:

- Visceral Adiposity Index (VAI)
- Homeostasis Model Assessment of Insulin Resistance (HOMA-IR)

Secondary end-point to evaluate the effect on inflammatory status:

- hs-C-Reactive Protein (hs-CRP) (mg/l)

4. STUDY DESIGN

The study will be randomized, double-blind, parallel-group, placebo-controlled: half of the subjects will be allocated to the active product and half of the subjects will be allocated to a placebo. Subjects will take the assigned food supplement for 84 days according to the directions for use.

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4.1. Randomization

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 generated randomization list.

4.2. Blinding

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 the products (see Annex 1).

5. INVESTIGATIONAL PRODUCTS

5.1. Composition

Active

Hops extract (*Humulus Lupulus L.*), Maltodextrin, Magnesium stearate, White size 0 capsule in HPMC

Allergens

None

Placebo

Maltodextrin, Magnesium stearate, Green colorant (E140), White size 0 capsule in HPMC

Allergens

None

The food supplement is compliant to the current national and international legislation (The sponsor is responsible for providing a statement to this regard).

5.2. Dosage and direction of use

Subjects will take one capsule per day, in the morning, on an empty stomach, with a glass of water.

5.3. Supply and storage

The products will be supplied by the Sponsor.
The shipment address is: Nutratech S.r.l. Via Francesco Todaro, 20/22 – 87036 Rende (CS).
The contact person is Alessandra Cersosimo (@:alessandra.cersosimo@nutratechtesting.com); T: +39 0984 173 5511.
Products will be stored at room temperature protected from direct light, heat and source of water safe place with restricted access.

6. STUDY POPULATION

6.1. Sample size

The study will be performed on 66 (60 + 6, considering a 10% drop-out) subjects.

6.1. Subjects' enrolment

Subjects are enrolled according to specific inclusion and exclusion criteria listed in the sections below.
All inclusion and exclusion criteria are checked by the Principal Investigator or designated personnel. The Principal Investigator maintains a record of all subjects who are enrolled and who are considered screen-failed (i.e., subject who signs the informed consent form and is not enrolled) and for each subject, the primary reason for not enrolling is recorded. Subjects enrolled are identified by a unique code that remains personal and cannot be associated to another subject during the study.

6.1.1. 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 (NHS)
7. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel

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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/m^2 and 34.9 kg/m^2 (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

6.1.2. 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

6.2. Subject withdrawal and discontinuation

In compliance with the Declaration of Helsinki, subjects have the right to withdraw from the study at any time and for any reason. In all cases, the Principal Investigator or designated personnel should try to contact the subject as soon as possible for a final assessment to: i) document the subject's decision on the informed consent form, ii) record the reason(s) for withdrawal on the data collection sheet, iii) evaluate the subject's clinical condition, if relevant iv) provide

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appropriate therapeutic measures if necessary (e.g., management of adverse events or concomitant conditions), v) collect any investigational product provided to the subject.
If a subject misses a scheduled visit, the Principal Investigator or designated personnel will attempt to contact the subject by phone on two separate occasions. If the subject cannot be reached after these attempts, they will be considered lost to follow-up. These contact attempts and their outcomes will be documented in the source document.
The Principal Investigator may also decide to withdraw a participant from the trial early if the subject no longer meets the eligibility criteria, fails to comply with the protocol, or is deemed unsuitable to continue the study. This may occur, for example, in the event of illness, pregnancy, or the occurrence of an Adverse Event (AE) or Serious Adverse Event (SAE), particularly if the Principal Investigator considers that the subject's health may be at risk or if concomitant treatments required are incompatible with the continuation of the trial. In such cases, the Sponsor will be notified immediately, and a detailed report explaining the reason for withdrawal will be forwarded as soon as possible. Any early termination related to an AE or SAE will be monitored until its resolution.
The sponsor has the right to exclude any subject from the trial for major protocol violations, administrative reasons, or other justifiable reasons.
However, a high dropout rate may compromise or invalidate the interpretability of the study. Therefore, premature exits without valid reasons should be minimized and carefully documented in the case report form, the final report, and, if applicable, in the AE form. Each premature exit will be categorized as follows: i) violation of inclusion and exclusion criteria, ii) occurrence of an AE, iii) occurrence of an SAE, iv) withdrawal of consent, v) lost to follow-up, vi) non-adherence to the protocol, vii) other reason (to be clearly specified).
Withdrawn/lost to follow-up/drop-out subjects will not be replaced.
Further details regarding safety reporting and management are provided in Paragraph 12.

6.3. Subject full participation

Study completion is achieved when a subject has completed all treatment and has attended all scheduled visits.

7. ETHICAL CONSIDERATIONS

7.1. Risk and benefit

The food supplement administered in this study is in compliance with current food legislation and is composed of ingredients with a well-established history of safe use in humans.
No adverse effects are expected under the indication of use. However, as with any food product, the possibility of individual reactions cannot be completely excluded. If applicable, information regarding the presence of any substances that may cause hypersensitivity will be provided prior to participation.
The potential benefits associated with the use of the product are related to the improvements of selected parameters related to metabolic syndrome.

7.2. Compliance with the Declaration of Helsinki

The study will be conducted in accordance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amendments).

7.3. Informed Consent

During the recruitment phase, the Principal Investigator or designated personnel will explain to each subject the nature, purpose, potential benefits, and possible risks of participation in the study. The investigator must ensure that the subject has understood all relevant aspects of the study. Sufficient time will be provided to allow questions to be asked and answered.
After this discussion, subjects will be asked to carefully read and sign the study information sheet, the informed consent form, and the privacy agreement pursuant to art. 13 of EU Regulation 2016/679.
The informed consent form, approved by the Sponsor, will be prepared in two versions: a version in English and a version in the local language, written in terms readily understandable to the subject. Only the version in the local language will be presented to and signed by study participants.
The informed consent form, approved by the Sponsor, will contain all required elements in language that is readily understandable to the subject. Each original consent form, personally signed and dated by both the subject and the investigator conducting the consent discussion, will be retained by the investigator. A copy will be provided to the subject. Subjects will be informed that they have the right to withdraw their consent.

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The consent form may need to be revised during the study, either because important new information has become available that may be relevant to the safety of the subjects, or because of protocol amendments. It is the investigator's responsibility to ensure that the amended form is signed by all subjects who are subsequently entered into the study, as well as by those who are already in it. This is documented in the same way as previously described.

7.4. Confidentiality and Data Protection

All information, data, and results of the study are strictly confidential, and all individuals with access to such data are informed of this obligation.

In accordance with the applicable law on data protection (EU Regulation 679/2016), the personal data, which may be special, including date of birth, sex, race, etc.., the information resulting from clinical studies and on health status are processed in confidence, only for research purposes in relation with this study. If the results arising from the clinical study should be published or disseminated in scientific journals or conferences, this is done in a manner that preserves confidentiality. For this purpose, relevant subject data may be forwarded to the Sponsor or its partners abroad. In each case, subject data will be pseudonymised and identified only by a code number and initials. The Principal Investigator will be responsible for maintaining the list of codes that links each subject's number with their identity.

In all cases, nominative information shall not be transmitted to the Sponsor. If a subject's name appears on a document required by the Sponsor (e.g., photographs), the name will be permanently blacked out by the site personnel, leaving only the initials visible and annotating the subject number for identification.

The data will remain strictly confidential and will not be made public. However, at any time during or after the study, health authorities may be granted direct access to the records to verify the accuracy of the collected information. In such cases, subject identity may be disclosed. All individuals granted access to these records are bound by professional secrecy.

8. STUDY SCHEDULE AND PROCEDURES

The study will last 84 ± 2 days. Clinical visits are planned at T-1 (initial visit), T0 (baseline visit), T56 (follow-up visit, after 56 ± 2 days of treatment) and at T84 (final visit, after 84 ± 2 days of treatment).

8.1 Timeline diagram

A schematic flow diagram is provided below:

8.2. Summary of study visits and procedures

The following table summarizes the planned visits and procedures:

Procedures	T-1	T0	T56	T84
Signature of informed consent and privacy statement of screened subjects	X	-	-	-
Verification of subject eligibility	X	X	X	X
Collection of subjects' demographic data and variables relevant to eligibility assessment	X	-	-	-
Randomization to treatment	-	X	-	-
Distribution of products	-	X	X	-
Distribution of diaries	-	X	X	-
Measurements of waist circumference, body weight, BMI – primary endpoints	-	X	X	X
Analysis of TC, HDL, LDL, TG, FG, FI – primary endpoints *	-	X	X	X
Analysis of HbA1c – primary endpoint *	-	X	-	X
Analysis of hs-CRP – secondary endpoint *	-	X	X	X

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Calculation of HOMA-IR, VAI – secondary endpoints	-	X	X	X
Collection and counting of products	-	-	X	X
Collection of diaries	-	-	X	X
Monitoring of Tolerability	-	◄———	———	———►

* Blood analysis will be performed in the morning following the visit

8.3. Initial visit (T-1)

Subjects to be enrolled will be screened in the volunteer's database by appropriate personnel (authorized by the investigator, pursuant to and for the effects of the legislation on protection of personal data) and invited to participate in the study.

At the initial visit, the Principal Investigator or designated personnel will assess whether each participant meets all inclusion and exclusion criteria and collect the subject's demographic data together with the variables relevant to eligibility assessment*. Subjects will be informed of the study procedure and will be asked to sign an informed consent form and an authorization for the personal data treatment.

The Principal Investigator or designated personnel will set the date of the baseline visit.

*The assessment of hematological variables relevant for eligibility will be performed subsequently: subjects will undergo blood tests at an external partner facility the following morning, while fasting.

8.4. Baseline visit (T0)

The Principal Investigator or designated personnel will assess whether each participant still meets all inclusion and exclusion criteria.

Waist circumference and body weight will be measured.

Blood analysis of TC, HDL, LDL, TG, FG, FI, HbA1c and hs-CRP will be perfomed. *

Calculation of BMI, HOMA-IR and VAI will be executed.

According to the previously defined randomization list, 66 subjects will receive the active product, and 66 subjects will receive the placebo product (enough for at least 56 days of treatment). Subjects will be advised to bring back the advanced products at the next visit.

During the study visit, participants will be asked to complete a retrospective dietary diary reporting their usual eating habits. This diary will be used together with the monitoring diaries completed at home to ensure that participants' dietary habits do not change during the study. Subjects will also be provided with diaries to ensure that they maintain their usual eating habits and physical activity throughout the study, and they will be instructed to return the completed diaries at the next visit.

Subjects will be instructed to take the food supplement in accordance with the usage instructions for 84 consecutive days.

The Principal Investigator or designated personnel will set the date of the follow-up visit.

*Subjects will undergo blood tests at an external partner facility, on the following morning, while fasting and prior to product intake.

8.5. Follow-up visit (T56: after 56 ± 2 days)

After 56 days (± 2 days) of product intake subjects will be visited by the Principal Investigator or designated personnel.

The Principal Investigator or designated personnel will assess whether each participant still meets all inclusion and exclusion criteria.

Waist circumference and body weight will be measured.

Blood analysis of TC, HDL, LDL, TG, FG, FI and hs-CRP will be perfomed. *

Calculation of BMI, HOMA-IR and VAI will be executed will be executed.

Subjects will return the completed diaries.

Subjects will receive new diaries and they will be instructed to return them at the final visit.

To assess the compliance, unused product samples will be collected and counted. Subjects will receive enough amount of the same product for at least 28 days of treatment, and they be advised to bring back the advanced products at the next visit.

The Principal Investigator or designated personnel will set the date of the final visit.

* Subjects will undergo blood tests at an external partner facility, on the following morning, while fasting and prior to product intake.

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8.6. Final visit (T84: after 84 ± 2 days)

After 84 days (± 2 days) of product intake subjects will be visited by the Principal Investigator or designated personnel.
The Principal Investigator or designated personnel will assess whether each participant still meets all inclusion and exclusion criteria.
The participants will return the completed diaries.
Waist circumference and body weight will be measured.
Blood analysis of TC, HDL, LDL, TG, FG, FI, HbA1c and hs-CRP will be perfomed. *
Calculation of BMI, HOMA-IR and VAI will be executed.
To assess the compliance, unused product samples will be collected and counted.
* Subjects will undergo blood tests at an external partner facility, on the following morning, while fasting.

NOTES:

The tolerability of the product will be monitored through the reporting of adverse events throughout the entire duration of the study (see paragraph 12).

9. TREATMENT COMPLIANCE

The Principal Investigator and designated personnel will keep a record of products given to subjects and unused products received by subjects during the visits.
Any returned product will be destroyed according to current internal procedures.

Compliance will be calculated as follows:

$$\text{Compliace to treatment} = \frac{\text{number of intake product}}{\text{number of product to intake}} \text{x}100$$

Subjects will be defined as compliant if they use 80 –120% of the treatment regimen over the 84-day period.

10. ENDPOINTS

10.1. End-points to evaluate the effect on anthropometric parameters

10.1.1. Waist circumference

Waist circumference is measured with a tape measure at the midpoint between the last visible rib and the top of the iliac crest and it is expressed in cm. Increased waist circumference is associated with higher risks of metabolic disorders.

10.1.2. Body weight

Body weight is measured using a scale. Measurements are expressed in Kg. Excessive body weight, especially when combined with high levels of body fat, is a risk factor for metabolic syndrome and associated conditions.

10.1.3. Body Mass Index (BMI)

Body Mass Index (BMI) is a parameter used to determine if a person is underweight, normal weight, overweight, or obese. High BMI values are linked to an increased risk of metabolic syndrome, diabetes, and cardiovascular diseases.
It is calculated using the formula: BMI = weight / height^2
where weight is in kilograms and height is in meters.

10.2. End-points to evaluate the effect on lipid metabolism

10.2.1. Total cholesterol (TC)

Total cholesterol is measured by blood analysis to evaluate overall lipid levels, and it is expressed in mg/dl. Elevated total cholesterol may indicate an increased risk of cardiovascular disease.

10.2.2. High-density lipoprotein cholesterol (HDL-C)

High-density lipoprotein cholesterol (HDL-C) is measured by blood analysis to assess "good" cholesterol levels, and it is expressed in mg/dl. Higher HDL-C levels are commonly associated with a lower risk of cardiovascular disease.

10.2.3. Low-density lipoprotein cholesterol (LDL-C)

Low-density lipoprotein cholesterol (LDL-C) is measured by blood analysis to assess "bad" cholesterol levels, and it is expressed in mg/dl. Elevated LDL-C levels may indicate an increased risk of cardiovascular disease.

10.2.4. Triglycerides (TG)

Plasma triglyceride concentration is measured by blood analysis, and it is expressed in mg/dl. High triglyceride levels may increase the risk of cardiovascular disease and metabolic disorders.

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10.3. End-points to evaluate the effect on carbohydrate metabolism

10.3.1. Fasting glucose (FG)

Fasting blood glucose is measured by blood analysis, and it is expressed in mg/dl. Elevated fasting glucose may indicate insulin resistance or a higher risk of developing diabetes.

10.3.2. Fasting Insulin (FI)

Fasting blood glucose is measured by blood analysis, and it is expressed in µU/ml. Elevated fasting insulin may suggest insulin resistance.

10.3.3. Glycated hemoglobin (HbA1c)

Glycated hemoglobin (HbA1c) is a measure of average blood glucose levels over the past 2-3 months, reflecting long-term glucose control. It is measured by blood analysis, and it is expressed in % or mmol/l. Higher HbA1c levels are associated with an increased risk of diabetes.

10.4. End-points to evaluate the effect on metabolic indices

10.4.1. HOMA-IR (Homeostasis Model Assessment of Insulin Resistance

The HOMA-IR (Homeostasis Model Assessment of Insulin Resistance) is a mathematical model used to assess the level of insulin resistance. A higher HOMA-IR value indicates greater insulin resistance, whereas lower HOMA-IR values suggest better insulin sensitivity.

It is calculated using the following formula:

$$\text{HOMA} - \text{IR} = \left(\frac{\text{Fasting Insulin} * \text{Fasting Glucose}}{405}\right)$$

Where Fasting Insulin is in (µU/mL) and Fasting Glucose is in (mg/dL).

10.4.2. Visceral Adiposity Index (VAI)

The Visceral Adiposity Index (VAI) is an empirical mathematical parameter, gender specific, indicator of visceral fat distribution and function.

It is calculated using the following formulas:

$$\text{Males VAI} = \left(\frac{\text{WC}}{39.6 + (1.88 * \text{BMI})}\right) * \left(\frac{\text{TG}}{1.03}\right) * \left(\frac{1.31}{\text{HDL}}\right)$$

$$\text{Females VAI} = \left(\frac{\text{WC}}{36.58 + (1.89 * \text{BMI})}\right) * \left(\frac{\text{TG}}{0.81}\right) * \left(\frac{1.52}{\text{HDL}}\right)$$

Where:
WC= waist circumference (cm)
BMI= body mass index
TG= triglycerides (mmol/l)
HDL= HDL cholesterol (mmol/l).

10.5. End-point to evaluate the effect on inflammatory status

10.5.1. hs-CRP

High-sensitivity C-Reactive Protein (hs-CRP) is measured through blood analysis to assess systemic inflammatory status and is expressed in milligrams per Liter (mg/l).

High hs-CRP levels indicate greater systemic inflammation, which is commonly associated with metabolic syndrome.

11. SUPPORT MATERIAL

None

12. SAFETY ASSESSMENT

The tolerability of the product will be closely followed by the study Principal Investigator during the study. Subjects will have access to the investigator via a contact phone number provided with the study information sheet in case of intolerance reactions. If a subject reports an event, the Principal Investigator will establish whether it is product-related. If so, report it as an adverse reaction. Any unexpected side effects related to the product will be reported to the sponsor. At the investigator's discretion, the subject may be withdrawn from the study, in which case the side effect will be monitored until it is resolved.

12.1. Causality assessment

There are five levels of causality that can be used to determine whether the event is related to the product.

- Very likely

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Clinical signs suggest a link with the product. The reaction follows a clear temporal sequence in relation to the time of product use and rechallenge is positive.

- Likely

Clinical signs suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product intake and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and rechallenge is positive. Or, clinical signs only partially suggest or do not suggest a link with the product, the reaction follows a definite reasonable temporal sequence from the time of the product intake and rechallenge is positive.

- Not clearly attributable

Clinical signs suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product intake and rechallenge is negative. Or clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product intake and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and rechallenge is positive.

- Unlikely

Clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and rechallenge is negative. Or clinical signs only partially suggest or do not suggest a link with the product; the time sequence between use of the product and occurrence of the symptoms is compatible; and rechallenge is negative. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product intake and rechallenge is negative.

- Excluded

Causality can only be excluded if another aetiology has been medically validated or if the time sequence between exposure and the occurrence of signs is incompatible. In case of adverse events, subjects can also contact the Principal Investigator or designated personnel if necessary. If required, they would be assessed by the specialist who would perform the clinical assessment and decide the appropriate measures to take (i.e. medical treatment, withdrawal …).

12.2. Recording and evaluation of adverse reactions

For each sign, intensity, location, duration (hours, minutes), and frequency are recorded. Moreover, the investigator collects all discomfort or reactions reported by the subjects. Each time a sign (physical or functional) appears (new sign or worsened compared to the baseline evaluation i.e. evaluation on the first day of the study), a reaction is recorded. All the reactions observed by the specialist and reported by the subject are recorded. The following information are recorded: i) subject characteristics, ii) details about study product (product code or name, date of first use, way of use), iii) description of the reaction (functional and physical signs, intensity of the signs, location, date/time of onset, timeframe between product use and onset of the reaction, date/time of end or duration (hours, minutes), frequency, diagnosis/nature of the reaction), iv) significant medical history , v) concomitant events: cutaneous diseases, medical treatments, products application, food, external factors (weather conditions), other diseases, vi) outcome and actions taken (way of use modification, temporary interruption, definitively discontinuation, medical treatment, care), and viii) relationship to the product (causality assessment). This assessment is done in conjunction with clinical expertise, and knowledge of the product (type of product, conditions of use…).

12.3. Documentation of Adverse Event and Serious Adverse Event

All Adverse Events considered likely to be related to the study product, as well as all Serious Adverse Events, will be documented in the data collection sheet and included in the report of the study. If no Adverse Events occur, the report will explicitly state that no side effects were observed during the study.

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12.4. Notification to the Sponsor

Any adverse events occurring during the study or after the study will be reported to the Sponsor's vigilance officer by e-mail (at carolina.galli@roelmihpc.com) with a copy to the project manager, using the appropriate notification forms. Serious adverse events will be reported within 24 hours of observation, and adverse events related to the product will be reported as soon as possible. If pictures of the reactions are available, these will be included in the notification.

12.5. Follow-up procedures

Any adverse events or serious adverse events related to the product will be followed up until they are resolved or stabilised. To inform the sponsor's vigilance officer of any new information, the investigator will use the appropriate forms, which will be filled in with the results collected from the examination carried out. Reports of hospitalisation will be enclosed with the notification form.

12.6. Definitions

Adverse Event (AE): An Adverse Event is any untoward medical occurrence in a clinical investigation subject administered a test product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a test product, whether related to the test product.

Serious Adverse Event (SAE): A Serious Adverse Event is any untoward medical occurrence that: i) results in death, ii) is life-threatening, iii) requires inpatient hospitalization or prolongation of existing hospitalization, iv) results in persistent or significant disability/incapacity, or v) is a congenital anomaly/birth defect.

13. DATA HANDLING AND RECORD KEEPING

13.1. Data collection

Data will be recorded in paper and/or electronic data collection sheets. The Principal Investigator, or appropriately qualified staff authorized by the Investigator, will be responsible for completing the data collection sheets. Paper forms will be completed in blue ballpoint pen, while electronic data capture will be performed using Microsoft® Office 365.
The Principal Investigator will review the data collection sheets and all adverse event reporting forms, attesting to the accuracy and completeness of the information. Any corrections made to the data collection sheets or source documents must be performed by the responsible staff member or an authorized delegate in a manner that does not obscure the original entry. For paper forms, all corrections must be dated and initialled by study site personnel. For electronic data capture, all modifications will be automatically tracked. Where the reason for a correction is not self-evident, an explanatory note must be provided.
Data entry and quality control will be performed by two different persons. The Principal Investigator remains ultimately responsible for all recorded data.
In line with Good Clinical Practice, the following definitions apply to clarify the nature and origin of recorded information:

- Source Data: all original records and certified copies of original records of clinical findings, observations, or other activities necessary for the reconstruction and evaluation of the trial. Source data are contained within source documents (i.e., original records or certified copies).
- Source Documents: original documents, data, and records, such as subject files, data collection sheets, notes, or evaluation checklists.

13.2. Quality assurance

All study-related files (including data collection sheets, the protocol, results, the final report, and other study documents) are subject to quality assurance procedures in compliance with regulatory requirements. Investigating sites authorize inspections by Regulatory Authorities and audits or controls by the Sponsor, granting access to raw data as needed.

13.3. Archiving and Retention

An original copy of all study documentation (signed protocol, Sponsor's safety assessment letter, case report forms, raw data, administrative file including all correspondence, etc.) will be retained in the records of Nutratech SrL for 10 years. The archives will only be destroyed after receipt of written and signed authorization from the Sponsor. However, documents will be kept for a longer period if required by applicable regulatory requirements or by agreement with the Sponsor. The Investigator must take appropriate measures to prevent accidental or premature destruction of these documents. Archiving arrangements will be defined at site close-out. The Sponsor will inform Nutratech SrL in writing when the documents are no longer required to be kept.

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14. STATISTIC

14.1. Study population for analysis

The analysis will be conducted on the Per Protocol population. The per-protocol (PP) population is defined as all subjects who will complete the study without any major protocol violations. Subjects will be excluded from the per-protocol population if: they miss the one or more evaluation visit; or they do not used the product properly during the study period (as reported by the subject itself).
Any drop-outs and the reason for each drop-out will be reported in the final report.

14.2. Descriptive analysis

Demographic data and eligibility variables will be collected and reported in a Microsoft® Excel spreadsheet together with the randomization list and will be summarized using: i) mean value and/or median value; ii) standard error and/or interquartile range; iii) minimum value; iv) maximum value.
Endpoint variables will be recorded in a Microsoft® Excel spreadsheet, graphically represented, and analysed using: i) mean value and/or median value; ii) standard error and/or interquartile range; iii) minimum value; iv) maximum value; v) individual variation or percentage variation versus baseline; vi) mean and/or median variation versus baseline.

14.3. Inferential statistical analysis

To assess the efficacy of the product, inferential statistical analyses will be performed on the endpoints.
For each endpoint, depending on the data distribution, appropriate parametric (e.g., two-way mixed ANOVA) or non-parametric (e.g. Friedman test, Wilcoxon signed-rank test, Mann–Whitney U test,) methods will be applied to compare active placebo groups and to evaluate their effect over time.
No inferential analysis by subgroup (e.g., sex, age) will be performed.
The significance level (α) will be set at 0.05 (two-sided). Where applicable, adjustments for multiple comparisons (e.g., Bonferroni correction) may be applied.
Statistical analysis will be performed using NCSS 10 data analysis (Copyright © 1983-2015, NCSS, LLC.) or RStudio (Copyright © 2009-2025 Posit Software, PBC).

15. ADMINISTRATIVE ASPECTS

15.1. Publication policy

The results of the study as well as any other data disclosed or generated in the context of the study are confidential. Any publication in relation to the study shall be subject to Sponsor's prior written approval and authorization of the Principal Investigator of the study.

15.2. Contractual and financial agreements

The Principal Investigator and the Sponsor sign a clinical study agreement prior to the start of the study, outlining overall sponsor and investigator responsibilities in relation to the study. Financial remuneration covers the cost per included subject, based on the calculated costs of performing the study assessments in accordance with the protocol, and the terms of payment are described in the contract.

15.3. Insurance

Product liability insurance may be provided by the Sponsor.

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ANNEX 1- Labelling

Nutratech SrL will affix on each product the following labels:

Figure 1. Active label

	Integratore alimentare	
Utilizzare in accordo con il modo d'uso Campione solo per test	N° lotto: L1X041125 - A Data di scadenza:_____ **NT0001644-25** Modo d'uso: assumere una capsula al giorno, al mattino, a stomaco vuoto, con un bicchiere d'acqua.	Nutratech SRL, a Complife Company Via Francesco Todaro 20/22 87036, Rende (CS) Tel. 378 303 7302
AVVERTENZE: --		

Figure 2. Placebo

	Integratore alimentare	
Utilizzare in accordo con il modo d'uso Campione solo per test	N° lotto: L1X041125 - B Data di scadenza: _____ **NT0001644-25** Modo d'uso: assumere una capsula al giorno, al mattino, a stomaco vuoto, con un bicchiere d'acqua.	Nutratech SRL, a Complife Company Via Francesco Todaro 20/22 87036, Rende (CS) Tel. 378 303 7302
AVVERTENZE: --		

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