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Bergavit™ clinical trial: the cholesterol-lowering activity of a food supplement containing a bergamot juice extract

Submission date
03/05/2022

Recruitment status
No longer recruiting

Registration date
05/05/2022

Overall study status
Completed

Last Edited
08/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to assess the lipid-lowering effect of a food supplement containing flavonoids from a bergamot juice extract (Bergavit™). The study is further aimed at assessing the effects of Bergavit™ on blood sugar, weight management, and the liver.

Who can participate?
Patients aged 40 to 70 years old with borderline cholesterol values (Asian subjects with LDL cholesterol ranging from 119 to 139 mg/dl or 100 to 159 mg/dl, Caucasian subjects with LDL cholesterol 160-190 mg/dl)

What does the study involve?
Participants are asked to attend clinic visits at screening and after 2, 3 and 4 months of product intake. During the screening visit, the medical doctor informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the participants then fix the date for the first visit. During the first visit, participants give a blood sample while the trial staff measures their weight, body mass index and waistline circumference. The participants are then randomly allocated to use the Bergavit™ food supplement or the placebo (dummy) product for 6 months. All the measurements/assessments are carried out using minimally invasive procedures. The total duration of each visit is 30 minutes. The study duration is 4 months with an intermediate check at 2, 3, and 4 months.

What are the possible benefits and risks of participating?
The potential benefits of participating are decreases in cholesterol, blood sugar and weight. All the ingredients included in the product are approved for their use in food supplements and are used at the permitted concentration. The potential risks associated with the use of the product are assumed to be mild to moderate and are not expected to pose a risk to health. Risks associated with the procedures involved in this study are judged as minor. All the precautions

will be taken to ensure that the risks would be the lowest possible. All the measurements carried out are minimally invasive and no skin side effects are expected from the measurement process.

Where is the study run from?
1. Nutratech srl spin-off Università della Calabria (Italy)
2. Complife (Beijing) testing technology Co. Ltd. (China)

When is the study starting and how long is it expected to run for?
January 2022 to June 2023

Who is funding the study?
BIONAP srl (Italy)

Who is the main contact?
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2. Dr Fabio Amone, fabio.amone@nutratechtesting.com (Italy)
3. Dr Giovanni Chen, giovanni.chen@complifegroup.cn (China)

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
H.E.HU.AC.NMS00.210.00.00_ IT0002159/22

Study information

Scientific Title
Cholesterol-lowering activity of a bergamot (Citrus bergamia) extract in Asian and Caucasian subjects: a randomized, double-blind, controlled study

Acronym
BERCL

Study objectives
The trial is aimed to evaluate the hypolipidemic effect of the test product in adult male and female, Asian and Caucasian subjects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/03/2022, Comitato Etico Di Ateneo (CEA) Università della Calabria (Via Pietro Bucci Cubo 15/D - 87036 Arcavacata di Rende (CS), Italy; +39 984 496940; cea@unical.it), ref: not applicable

Study design
Randomized double-blind placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Borderline cholesterol values

Interventions
The active intervention (Bergavit™) is an extract containing the main flavonoids of Bergamot (Citrus bergamia) juice; while the placebo intervention is maltodextrin. Both the active (150 mg /die of pure flavonoids) and the placebo products are used as follows: one capsule per day intake after lunch or after dinner. Half of the test subjects will be randomized to receive the test

product and half of the test subjects will be randomized to receive the placebo product. A restricted randomization list will be created using PASS 2008 (PASS, LLC. Kaysville, UT, USA) statistical software running on Windows Server 2008 R2 Standard SP1 64-bit Edition (Microsoft, USA) by a biostatistician and stored in a safe place. The randomization sequence will be stratified using “Efron’s biased coin” algorithm with a 1:1 allocation ratio. The allocation sequence will be concealed from the in-site study director in sequentially numbered, opaque, and sealed envelopes, reporting the unblinded treatment allocation (based on the subject entry number in the study). The A4 sheet reporting the unblinded treatment will be folded to render the envelope impermeable to intense light. A masked allocation sequence will be prepared for the staff delivering the intervention based on the subject entry number in the study.

Participants are asked to attend clinic visits at screening and after 2, 3 and 4 months of product intake. During the screening visit, the medical doctor informs the participants about the trial procedure, risks, and benefits. Only participants giving their informed consent are enrolled in the study. The trial staff and the participants then fix the date for the first visit. During the first visit, participants give a blood sample while the trial staff measures their weight, body mass index and waistline circumference. The participants are then randomly allocated to use the Bergavit™ food supplement or the placebo (dummy) product for 6 months. All the measurements/assessments are carried out using minimally invasive procedures. The total duration of each visit is 30 minutes. The study duration is 4 months with an intermediate check at 2, 3, and 4 months.

Intervention Type
Supplement

Primary outcome(s)
Hypolipidemia (blood concentration of LDL, HDL, total cholesterol, ox-LDL, and triglycerides) measured by a blood test at screening and after 2, 3, and 4 months of intake

Key secondary outcome(s))
1. Hypoglycemia (fasting glucose blood concentration) measured by a blood test at screening and after 2, 3, and 4 months of intake
2. Weight measured by a balance at screening and after 2, 3, and 4 months of intake
3. Hepatoprotective activity (blood concentration of AST, ALT, AST/ALT and GTP) measured by a blood test at screening and after 2, 3, and 4 months of intake
4. Blood testing to evaluate the following parameters at screening and after 2, 3, and 4 months of intake: HbA1c, HOMA-IR, HOMA-β, ApoA-I, Apo B, Atherogenic index, Paraoxonase activity, D-Rom test, TNF-α (or C-reactive protein), creatine, insulin
5. Blood pressure measured by a digital sphygmomanometer at screening and after 2, 3, and 4 months of intake

Completion date
30/06/2023

Eligibility

Key inclusion criteria
1. Healthy men and women (40-70 years old)
2.1. Asian subjects with LDL-cholesterol (ranging from 100 to 159; see here below), triglycerides 150-199 mg/dl, BMI 25-29.9 kg/m², glycemia 100-130 mg/dl, fatty liver index (FLI) 30-60
2.2. Caucasian subjects with LDL cholesterol from 160-190 mg/dl, BMI 25-29.9 kg/m², glycemia

100-130 mg/dl, FLI 30-60
3. Subjects naïve to statins or other treatments and food supplements that can interfere with the study treatment for the previous month
4. Reading, understanding and signing approval of the informed consent
5. Non-vegetarian
6. Subjects who will continue, expect reserve, their normal lifestyle
7. Healthy volunteers without clinical illnesses with a relevant effect on the gastrointestinal system or visceral motility
8. Not pregnant
9. Non-smokers
10. Available and willing to follow the procedure of the study protocol

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
64

Key exclusion criteria
1. Subjects <40 and >70 years old
2. Clinical history with the relevant presence of any disorder or administration of drugs/food supplement that can potentially interfere with the treatment under study
3. Lack of compliance defined as not using the correct Bergavit dose or placebo for>1 week), and inability to give informed consent
4. Subjects who have changed their diet significantly or have been placed on weight reduction products
5. Smokers, obesity
6. Changing the eating habits within the 2 weeks before the screening
7. During the pregnancy of the subjects or of the subjective planning of the study
8. Subject during breastfeeding
9. Subjects with a history of drug, alcohol and other substance abuse
10. The participants who anticipate a change in their lifestyle or physical activity
11. Known food intolerance or food allergy
12. Subjects involved in a clinical or food study within the previous month
13. Subjects who have unstable medical diseases (cardiac arrhythmias or ischemia, uncontrolled hypertension and hypotension, diabetes mellitus, kidney failure)
14. Subjects with a history of paralysis or cerebral vascular accident
14. Subjects with active cancers or on chemotherapy
15. Subjects who have been under diuretics for the previous month
16. Other factors that limit their ability to cooperate during the study

Date of first enrolment

10/05/2022

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
China

Italy

Study participating centre
Nutratech srl spin-off Università della Calabria
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Study participating centre
Complife (Beijing) testing technology Co. Ltd.
Beizhan North Street N.17, Room 902 - Xicheng District
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Sponsor information

Organisation
BIONAP srl

Funder(s)

Funder type
Industry

Funder Name
BIONAP srl

Results and Publications

Individual participant data (IPD) sharing plan

Raw data will be stored on Complife servers. A backup copy of the raw data will be also in a cloud-based backup server. Tables containing the raw data (output of the measurements) will be also included in the study report and shared with the study sponsor by a pdf file electronically signed. The raw data will be stored for a minimum period of 10 years on Complife servers. In the raw data tables, subjects are identified by a means of a code generated by the Complife volunteer's management software. The code is composed of a letter, four digits, and a letter. Access to the study raw data is allowed only to the study director and the person designated by him to elaborate the raw data. Elaboration of the raw data includes descriptive statistics (mean and standard error) and inferential analysis (data normality and statistical test).

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/11/2024	08/07/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes