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Study of the effects of a nutraceutical combination product including the antioxidant bergamot polyphenolic fraction in patients with high normal blood pressure

Submission date
08/11/2024

Recruitment status
No longer recruiting

Registration date
19/11/2024

Overall study status
Completed

Last Edited
12/11/2024

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
High normal blood pressure (HNBP) is a borderline condition that necessitates lifestyle changes to lower the risk of cardiovascular disease in patients. Hypertension treatment often involves the use of natural derivatives, especially for HNBP, as part of an early intervention plan. This study will assess the effectiveness of Bergapress supplementation in individuals with HNBP and normal ejection fraction. The clinical administration of Bergapress in HNBP patients could lead to improved cardiovascular performance, primarily through the modulation of blood pressure levels, enhancement of endothelial function, and reduction of oxidative stress.

Who can participate?
Patients with HNBP and heart failure with preserved ejection fraction

What does the study involve?
Blood pressure assessment included DBP (diastolic blood pressure), SBP (systolic blood pressure) measurement and PP (pulse pressure) calculation; echocardiographic determinations of diastolic function and EndoPAT analysis will be performed to correlate cardiac functionality with endothelial dysfunction. Finally, the determination of serum malondialdehyde (MDA) will be performed to assess oxidative stress. These measurements will be carried out before and 90 days after starting treatment with a placebo or Bergapress at a dose of 1 g in 1 tablet, daily.

What are the possible benefits and risks of participating?
The possible benefits to subjects enrolled in the study and supplemented with Bergapress in subjects with HNBP could enhance cardiac performance, through the significant decrease of blood pressure levels, by improving endothelial function and reducing oxidative stress. The potential risks are minimal or nonexistent because the components of the extract have been traditionally used in medicine to treat a range of disorders, reducing oxidative stress, inflammation, endothelial dysfunction ameliorating lipid profile.

Where is the study run from?
Metabolic Diseases Clinic of the I S San Raffaele in collaboration with the Center for Hypertension at the Sant'Andrea Hospital of the La Sapienza University of Rome, Italy

When is the study starting and how long is it expected to run for?
November 2018 to December 2023

Who is funding the study?
The Italian Ministry of Research, Italy

Who is the main contact?
Dr Roberta Macri, roberta.macri@unicz.it, robertamacri85@gmail.com

Contact information

Type(s)
Scientific

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Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3032024, Italian Ministry of Research grant numbers PON-MIUR 03PE000_78_1 and PON-MIUR 03PE000_78_2

Study information

Scientific Title
Study of the effects of a nutraceutical combination product including the antioxidant bergamot polyphenolic fraction in patients with high normal blood pressure: a double-blind, randomized, placebo-controlled study

Acronym
Bergapress

Study objectives
Based on the evidence existing, about the protective key role of flavonoids to counteract several metabolic alterations, including endothelial dysfunction and hypertension, it is hypothesized that Bergapress (developed by H&D s.r.l. containing Orthosiphon stamineus Benth., Berberis aristata L., Olea europaea L. and bergamot polyphenolic fraction) will counteract oxidative stress and endothelial dysfunction, ameliorating systolic function and BP levels, in a population of 60 subjects with HNBP and normal ejection fraction, suffering from HFpEF.

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 24/11/2018, Calabria Region - Ethical Committee (Viale Europa - Cittadella Regionale - Località Germaneto, Catanzaro, 88100, Italy; +39 3343247595; palma@unicz.it), ref: 234/2018

Study design
Single-centre double-blind randomized placebo-controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Laboratory, Medical and other records

Study type(s)
Diagnostic, Prevention, Quality of life, Treatment, Safety, Efficacy

Participant information sheet
Not applicable

Health condition(s) or problem(s) studied
High normal blood pressure (HNBP) and heart failure with preserved ejection fraction (HFpEF)

Interventions
A single-centre double-blind, randomized, placebo-controlled study will be conducted on a population of 60 subjects with HNBP and normal ejection fraction on echocardiographic examination, suffering from HFpEF. In all patients, the presence of HFpEF will be defined as the presence of signs and symptoms of HF according to the 2019 guidelines of the Heart Failure Association of the ES, and in particular left ventricular ejection fraction ≥ 5% on echocardiographic examination and at least one of the following criteria: dilated left atrium (left atrial volume index ≥ 34 ml / m2) or evidence of diastolic dysfunction by tissue Doppler (E/e ' < 8).

The outcome of the treatment will be verified 90 days after treatment with a placebo or Bergapress at a dose of 1 g in 1 tablet, daily. The patients will be enrolled at the Metabolic Diseases clinic of the I S San Raffaele in collaboration with the Center for Hypertension at the Sant'Andrea Hospital of the La Sapienza University of Rome. All subjects will provide written informed consent at enrollment and the protocol was approved by the local ethics committee and met all principles of the Declaration of Helsinki. Patients with evidence of previous or current concomitant valvular disease will be excluded. Fasting blood samples will be taken from all patients both at time 0 (before administration of Bergapress or placebo) and day 90 after treatment. Care will be taken to ensure that the patients maintain the same dietary regime during the observation period. In analogy with the sampling, on the day of the visit at time 0 and after 90 days, to define the degree of arterial hypertension, the patients performed blood pressure measurement, echocardiographic examination, vascular reactivity test using the Endopat method and additional sampling to determine the serum malondialdehyde (MDA) levels.

Intervention Type

Supplement

Primary outcome measure
1. Cardiac performance measured using echocardiographic examination at baseline and day 90
2. Blood pressure measured using sphygmomanometry at baseline and day 90

Secondary outcome measures
Reduction of oxidative stress and endothelial dysfunction measured using endoPAT analysis and serum malondialdehyde (MDA) levels (a specific marker of oxidative stress) measured using the reactivity of thiobarbituric acid (TBA) as MDA used to assess oxidative stress through spectrophotometric quantification at baseline and day 90

Overall study start date
24/11/2018

Completion date
31/12/2023

Eligibility

Key inclusion criteria
Patients with High Normal Blood Pressure (HNBP) and Heart Failure with preserved ejection fraction (HFpEF)

Participant type(s)
Patient

Age group
Mixed

Lower age limit
60 Years

Upper age limit
79 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
Patients with evidence of previous or current concomitant valvular disease

Date of first enrolment
01/01/2019

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Italy

Study participating centre
Metabolic Diseases clinic of the I S San Raffaele in collaboration with the Center for hypertension at the Sant'Andrea Hospital of the La Sapienza University of Rome
Via di Val Cannuta, 247
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Sponsor information

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Magna Graecia University

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Sponsor type
University/education

Website
https://web.unicz.it

ROR
https://ror.org/0530bdk91

Funder(s)

Funder type
Government

Funder Name
Ministero dell'Università e della Ricerca

Alternative Name(s)
Ministry for Universities and Research, Italy, Ministry for Universities and Research, Ministero Università e Ricerca, Italian Ministero Università e Ricerca, MUR, M.U.R.

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Publication and dissemination plan
Planned publication in a peer-review journal

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Roberta Macri, roberta.macri@unicz.it, robertamacri85@gmail.com. The data that will be shared concerns the clinical status of the patient following the scheme of the inclusion and exclusion criteria, maintaining their anonymity, as explicitly stated in the documentation relating to the presentation of the ethics committee. Furthermore, the results obtained for each patient will also be made available, always anonymously. The consent from participants was obtained.

IPD sharing plan summary
Available on request