

# Bergamot and Cardoon extract for liver disease

<b>Submission date</b> 05/08/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/08/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/09/2023	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Non-alcoholic fatty liver disease is the most common cause of liver-related morbidity and mortality in the world. However, no effective drug treatment for this condition has been found. Oxidative stress is one of the key mediators of liver damage and represents a major contributor to the progression from simple steatosis to cirrhosis. It has been demonstrated that Bergamot (*Citrus bergamia* Risso et Poiteau) flavonoids decrease liver inflammation. Wild cardoon (*Cynara cardunculus* L.), is rich in antioxidant compounds which possess anti-inflammatory properties. The aim of this study is to test the effect of a new nutraceutical containing natural bioactive components from Bergamot and wild Cardoon, with antioxidant proprieties, as a treatment for patients with liver steatosis.

### Who can participate?

Patients aged 30 and over with liver steatosis

### What does the study involve?

Participants are randomly allocated to the intervention group or the control group. The intervention group receive Bergacyn®, containing a Bergamot polyphenol fraction and *Cynara Cardunculus* extract, for 12 weeks. The control group receive a placebo (dummy pill) daily for 12 weeks. Liver fat content is measured at the start and the end of the study.

### What are the possible benefits and risks of participating?

All participants receive a liver disease screening for free. No risks are expected.

### Where is the study run from?

University Magna Grecia (Italy)

### When is the study starting and how long is it expected to run for?

June 2018 to September 2019

### Who is funding the study?

Ministry of Education, Universities and Research (Italy)

### Who is the main contact?

1. Prof. Arturo Pujia

Pujia@unicz.it  
2. Prof. Vincenzo Mollace  
Mollace@unicz.it

## Contact information

### Type(s)

Scientific

### Contact name

Prof Arturo Pujia

### Contact details

viale Europa Campus S. Venuta, Magna Grecia University  
sn  
Catanzaro  
Italy  
88100  
+39 (0)3316718206  
pujia@unicz.it

### Type(s)

Scientific

### Contact name

Prof Vincenzo Mollace

### Contact details

Research Centre for Food Safety and Health (IRC-FSH)  
viale Europa  
Campus S. Venuta  
Magna Grecia University  
Catanzaro  
Italy  
88100  
+39 (0)3316718386  
mollace@unicz.it

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

219/2018/CE

# Study information

## Scientific Title

Effects of Bergamot (Citrus bergamia Risso et Poiteau) and wild cardoon (Cynara cardunculus L.) extract intake on non-alcoholic fatty liver disease (NAFLD)

## Study objectives

Given the key roles of oxidation and inflammation in the pathogenesis of liver steatosis and the promising role for natural antioxidants, in this study the aim was to test the effect of a new nutraceutical containing Bergamot and wild Cardoon extract.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 24/09/2018, local ethical committee at the "Mater Domini" Azienda University Hospital (viale T. Campanella, Catanzaro, Italy; Tel: +39 (0)961 712 111; Email: comitatoetico@hotmail.it; michelangelo.rossano@regione.calabria.it), ref: 219/2018/CE

## Study design

Double-blind placebo-controlled randomized clinical trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

## Health condition(s) or problem(s) studied

Liver steatosis

## Interventions

Participants are randomized by simple randomization to:

1. Bergacyn® (provided by Herbal & Antioxidant SRL, Bianco, RC, Italy): one softgel pill containing 300 mg of a combination product containing bergamot polyphenolic fraction (BPF®), and wild type Cynara Cardunculus extract plus excipients including PUFA 380 mg and a mixture of bergamot pulp and albedo derivative]. (registered Patents RM2008A000615, PCT/IB2009/055061 and 102017000040866)
2. Placebo: one softgel pill containing maltodextrin 300 mg plus excipients including PUFA 380 mg

Both groups receive the intervention for 12 weeks. Liver fat content, measured by transient elastography (Fibroscan), serum transaminases, lipids and glucose will be measured at the baseline and the end of the study.

### **Intervention Type**

Supplement

### **Primary outcome measure**

Liver fat content and/or liver steatosis markers measured by transient elastography (Fibroscan) at baseline and after 12 weeks

### **Secondary outcome measures**

Measured at baseline and after 12 weeks:

1. Disease progression measured by liver elastography
2. Insulin resistance measured by colorimetric test
3. Lipids in blood measured by colorimetric test
4. PCSK9 modulation measured by ELISA/colorimetric test
5. Inflammatory markers measured by colorimetric test
6. Endothelial function and other hemodynamic parameters measured by Endo-PAT

### **Overall study start date**

01/06/2018

### **Completion date**

30/09/2019

## **Eligibility**

### **Key inclusion criteria**

1. Over 30 years old
2. Both genders
3. Liver steatosis defined by CAP score over 216 dB/m

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Lower age limit**

30 Years

### **Sex**

Both

### **Target number of participants**

102

### **Total final enrolment**

**Key exclusion criteria**

1. Past and current alcohol abuse
2. Clinical and laboratory signs of chronic hepatitis B and/or C virus infection
3. Allergies to cardoon, artichoke or maize
4. Triglycerides concentration over 250 mg/dl
5. Autoimmune or cholestatic liver disease
6. Liver cirrhosis
7. Pregnancy
8. Nephrotic syndrome
9. Chronic renal failure
10. Gastroesophageal reflux
11. Cancer
12. Taking amiodarone, antiretroviral agents, corticosteroids, methotrexate, tamoxifen, valproate. The study's protocol allowed to enrol only long-term lipid-lowering drugs users (more than 6 weeks)

**Date of first enrolment**

11/02/2019

**Date of final enrolment**

10/04/2019

**Locations****Countries of recruitment**

Italy

**Study participating centre**

**Clinical Nutrition Unit of the "Mater Domini" Azienda University Hospital**  
viale Europa , Campus S. Venuta, University Magna Grecia  
Catanzaro  
Italy  
88100

**Sponsor information****Organisation**

Italian Ministry of University and Research (MIUR)

**Sponsor details**

viale G. Ribotta 5  
Rome  
Italy

00144  
+39 06 59941  
minsalute\_estero.dgprog@sanita.it

**Sponsor type**  
Government

**Website**  
[www.salute.gov.it](http://www.salute.gov.it)

**ROR**  
<https://ror.org/0166hxq48>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Ministero dell'Istruzione, dell'Università e della Ricerca Nutramed Project, PON 03PE000\_78\_1

**Alternative Name(s)**  
Ministry of Education, University and Research, Ministry of Education, Universities and Research, Italian Ministry for Universities and Research, Italian Ministry for Education, University and Research, Italian Ministry of Education, MIUR

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
Italy

## **Results and Publications**

**Publication and dissemination plan**  
Publication in journal in English with impact factor; mass media.

**Intention to publish date**  
02/06/2019

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Pujia (Pujia@unicz.it).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	11/08/2020	02/09/2020	Yes	No
<a href="#">Results article</a>		26/11/2022	06/09/2023	Yes	No