

Effect of LIVOGEN, a nutraceutical containing natural bioactive components bergamot extract, artichoke leaf extract, Nigella sativa, EPA, DHA and silybin, on individuals affected by liver steatosis (fatty liver disease)

| | | |
|--|---|---|
| Submission date 03/08/2021 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 02/09/2021 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 22/08/2022 | Condition category Digestive System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Non-alcoholic fatty liver disease (liver steatosis) is the most common cause of liver-related illness and death in the world. However, no effective drug treatment for this condition has been found. It has been demonstrated that Bergamot Bioactive Polyphenolic Fractions (BPF) associated to wild Cardoon, can reduce liver steatosis in subjects over 50 years. The aim of this study is to test the effect of a new nutraceutical containing natural bioactive components of Bergamot ext (BPF), Artichoke Leaf ext, Nigella Sativa, EPA, DHA, Silybin, etc (namely LIVOGEN) 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 receives Livogen Plus® for 12 weeks. The control group receives 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. There are no risks for participants.

Where is the study run from?

University Magna Grecia (Italy)

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

October 2020 to December 2022

Who is funding the study?
Tishcon Corporation, Westbury, NY & Salisbury, MD (USA)

Who is the main contact?
Prof. Tiziana Montalcini, tmontalcini@unicz.it

Contact information

Type(s)
Scientific

Contact name
Prof Tiziana Montalcini

ORCID ID
<https://orcid.org/0000-0001-7048-5830>

Contact details
viale Europa
Catanzaro
Italy
88100
+39 961 3697314
tmontalcini@unicz.it

Additional identifiers

Protocol serial number
n. 330, 22 October 2020

Study information

Scientific Title
LIVOGEN in liver steatosis

Acronym
LILIST study

Study objectives
The aim of the present study is to test the effect of a new nutraceutical containing natural bioactive components as Bergamot ext, Artichoke Leaf ext, Nigella Sativa, EPA, DHA, Silybin, etc (namely LIVOGEN) as treatment in individuals with liver steatosis.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 22/10/2020 il Comitato Etico Regione Calabria Sezione Area Centro con sede presso (l' A.O.U. Mater Domini in Via Tommaso Campanella, 115 Catanzaro, Italy; +39 (0)961 712 111; comitatoetico@hotmail.it), ref: 330/2020/CE

Study design

Interventional randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Liver steatosis

Interventions

Participants will be enrolled after a written informed consent will be obtained and will be randomly assigned (by computer-generated random numbers) in a 1:1 ratio to receive either the nutraceutical or a placebo for up to 12 weeks

The nutraceutical and placebo softgel capsules will be supplied by the Thishcon corp. The capsules will be similar in shape, size, and color. The Livogen Plus® study dose are the follow: 6 softgels daily, 3 with each main meal (lunch and dinner). The same for placebo. The enrollment period will be of at least 18 months. We will assess the CAP score by Elastography (Fibroscan). The treatment period will last 3 months.

Intervention Type

Supplement

Primary outcome(s)

1. CAP score value will be measured by Fibroscan at baseline and after 12 weeks of treatment
 2. Serum lipid (cholesterol, HDL-cholesterol, and triglycerides) profile will be assessed by chemiluminescent immunoassay at baseline and after 12 weeks of treatment
 3. AST, ALT, and GGT will be measured by chemiluminescent immunoassay at baseline and after 12 weeks of treatment
- Insulin will be determined by chemiluminescent immunoassay at baseline and after 12 weeks of treatment
4. C-reactive protein (CRP) will be measured by chemiluminescent immunoassay at baseline and after 12 weeks of treatment.
 5. Serum interleukin-1 β (IL-1 β), interleukin-6 (IL-6), and tumor necrosis factor α (TNF- α) will be determined by sandwich enzyme-linked immunosorbent assay (ELISA) at baseline and after 12 weeks of treatment at baseline and after 12 weeks of treatment.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. NAFLD defined by a CAP score value ≥ 247 dB/m
2. Age 30 - 75 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

140

Key exclusion criteria

1. Taking nutraceuticals, supplements or functional food
2. Past and current alcohol abuse
3. Clinical and laboratory signs of chronic hepatitis B and/or C virus infection
4. Allergies to nutraceuticals components
5. Diabetes
6. Autoimmune or cholestatic liver disease, liver cirrhosis,
7. Pregnancy
8. Nephrotic syndrome, chronic renal failure
9. Gastroesophageal reflux
10. Cancer
11. Taking amiodarone, antiretroviral agents, corticosteroids, methotrexate, tamoxifen, valproate
12. Starting lipid-lowering drugs in the past month

Date of first enrolment

12/07/2021

Date of final enrolment

08/10/2021

Locations

Countries of recruitment

Italy

Study participating centre

University Magna Grecia of Catanzaro
Nutrition Unit of the "Mater Domini" Azienda University Hospital
Viale Europa
Campus Universitario S. Venuta
Catanzaro
Italy
88100

Sponsor information

Organisation

Tishcon (United States)

ROR

<https://ror.org/0133gy560>

Funder(s)

Funder type

Industry

Funder Name

Tishcon Corporation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request from Tiziana montalcini, tmontalcini@unicz.it; as SPSS dataset; it will become available from January 2023 upon journal request in the case of publication, after company approval only for data anonymisation.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 19/08/2022 | 22/08/2022 | Yes | No |