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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

Registration date
02/09/2021

Overall study status
Completed

Last Edited
22/08/2022

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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 12weeks. 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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-1β (IL-1β), 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.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
22/10/2020

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

Age group
Adult

Sex
Both

Target number of participants
140

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
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Sponsor information

Organisation
Tishcon (United States)

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Sponsor type
Industry

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ROR
https://ror.org/0133gy560

Funder(s)

Funder type
Industry

Funder Name
Tishcon Corporation

Results and Publications

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

Intention to publish date
30/01/2023

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