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Calabrian functional tomato sauce for the treatment of non-alcoholic fatty liver disease

Submission date
27/05/2025

Recruitment status
No longer recruiting

Registration date
04/06/2025

Overall study status
Completed

Last Edited
03/06/2025

Condition category
Digestive 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
Non-alcoholic fatty liver disease (liver steatosis) is the most common cause of liver-related illness and death worldwide. However, no approved drug treatments currently exist for this condition. Lycopene, a powerful antioxidant found in tomatoes, has shown potential benefits for liver health. OsteoCol® is a lycopene-enriched tomato sauce obtained through on-vine ripening, which increases its natural lycopene content. This study aims to evaluate the effect of daily consumption of OsteoCol® tomato sauce as a functional food for the treatment of patients with liver steatosis.

Who can participate?
Adult patients adults of both genders, aged 30-75 years, with a diagnosis of NAFLD.

What does the study involve?
Participants are allocated with a simple randomization using computer-generated random numbers to the intervention or the control group. Ninety-eight adults were randomly assigned to two groups for 12 weeks, as follows:
Intervention group: Participants received a functional tomato sauce (OsteoCol®), naturally enriched with lycopene. Twenty-five participants consumed 80 g/day, while twenty-four participants consumed 160 g every other day.
Control group: Participants received a commercial tomato sauce. Twenty-five participants consumed 80 g/day, while twenty-four participants consumed 160 g every other day.
The primary outcome measured was a change in the amount of intrahepatic fat, assessed by CAP score, after a 12-week intervention between groups.

What are the possible benefits and risks of participating?
The potential benefit is a reduction in the amount of liver fat and an improvement in the severity of NAFLD. There are no risks to 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?
From April 2022 to August 2023.

Who is funding the study?
This study was supported by a Grant from Calabria Region, Italy (Bando INGEGNO - POR CALABRIA FESR-FSE 2014/2020-SALNAF “Functional Calabrian Tomato Sauce Naturally Rich in Lycopene for the Treatment of Non-Alcoholic Fatty Liver Disease”).

Who is the main contact?
Prof. Arturo Pujia, pujia@unicz.it

Contact information

Type(s)
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
124/2022/CE

Study information

Scientific Title
SALNAF – Calabrian functional tomato sauce naturally rich in lycopene for the treatment of non-alcoholic fatty liver disease

Acronym

SALNAF

Study objectives
Non-alcoholic fatty liver disease (liver steatosis) is the most common cause of liver-related illness and death worldwide. However, no approved drug treatments currently exist for this condition. Lycopene, a powerful antioxidant found in tomatoes, has shown potential benefits for liver health. OsteoCol® is a lycopene-enriched tomato sauce obtained through on-vine ripening, which increases its natural lycopene content. This study aims to evaluate the effect of daily consumption of OsteoCol® tomato sauce as a functional food for the treatment of patients with liver steatosis.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/04/2022, Comitato Etico Regione Calabria Sezione Area Centro (A.O.U. Mater Domini in Via Tommaso Campanella, 115, Catanzaro, 88100, Italy; +39 (0)961 712 111; comitatoetico@hotmail.it), ref: 124/2022/CE

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Treatment of hepatic steatosis in patients with NAFLD

Interventions
Participants were enrolled after providing written informed consent and were randomly assigned (by computer-generated random numbers) in a 1:1 ratio to one of two treatment groups:
Intervention group: Participants received a functional tomato sauce (OsteoCol®), naturally enriched with lycopene. Twenty-five participants consumed 80 g/day, while twenty-four participants consumed 160 g every other day.
Control group: Participants received a commercial tomato sauce. Twenty-five participants consumed 80 g/day, while twenty-four participants consumed 160 g every other day

Intervention Type

Other

Primary outcome measure
Amount of intrahepatic fat (i.e. Controlled Attenuation Parameter value, CAP score), assessed by Transient Vibration-Controlled Elastography (Fibroscan), at baseline and 12 weeks

Secondary outcome measures
At baseline and 12 weeks:
1. Severity of NAFLD, assessed by FibroScan
2. LDL-cholesterol, measured using biochemical assays, after 12 weeks of treatment
3. Inflammation markers, measured using biochemical assays, after 12 weeks of treatment
4. Lipid accumulation (i.e., Lipid Accumulation Product, LAP) and cardiovascular risk markers (i.e., Atherogenic Index of Plasma, AIP)
5. Antioxidant status parameters, evaluated using ELISA kits

Overall study start date
21/04/2022

Completion date
29/08/2023

Eligibility

Key inclusion criteria
1. NAFLD defined by a CAP score value ≥248 dB/m
2. Age 30 - 75 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
30 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
98

Total final enrolment
98

Key exclusion criteria

1. Alcohol intake >30 g/day for men or >20 g/day for women
2. BMI ≥ 35 kg/m²
3. Allergy to tomatoes and nickel
4. HBV, HCV, HIV infection
5. Pregnancy
6. Type 2 Diabetes Mellitus (T2DM)
7. Triglycerides > 250 mg/dL
8. Gastroesophageal reflux disease
9. Hepatic and renal failure
10. Cirrhosis of the liver and other chronic liver diseases
11. Gallstones
12. Chronic intestinal diseases
13. Chronic debilitating diseases
14. Parenteral nutrition
15. Use of specific drugs (amiodarone, antiretrovirals, corticosteroids, methotrexate, tamoxifen, valproate, or lipid-lowering drugs for less than 6 weeks)
16. Use of food supplements or functional foods aimed at reducing hepatic steatosis

Date of first enrolment
27/03/2023

Date of final enrolment
31/05/2023

Locations

Countries of recruitment
Italy

Study participating centre
Nutrition Unit of the “R. Dulbecco” Azienda University Hospital
Viale Europa - Campus Universitario S. Venuta
Catanzaro
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88100

Sponsor information

Organisation
Regione Calabria

Sponsor details
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Sponsor type
Government

Website
https://www.regione.calabria.it

ROR
https://ror.org/03swz0133

Funder(s)

Funder type
Government

Funder Name
Regione Calabria - SALNAF - CUP: J39J22005540005

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
01/06/2025

Individual participant data (IPD) sharing plan
Individual participant data (IPD) that underlie the results reported in the main publication (including baseline data, primary outcomes, and secondary outcomes) will be made available after de-identification. The data will be accessible beginning 6 months after publication and for up to 5 years, to researchers who provide a methodologically sound proposal. Data will be shared in accordance with participant consent and applicable ethical guidelines. A data-sharing agreement may be required. Requests should be directed to pujia@unicz.it.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			03/06/2025	No	Yes