

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

Submission date 27/05/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/06/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/06/2025	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

30 years

Upper age limit

75 years

Sex

All

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

Italy

88100

Sponsor information

Organisation

Regione Calabria

ROR

<https://ror.org/03swz0133>

Funder(s)

Funder type

Government

Funder Name

Regione Calabria - SALNAF - CUP: J39J22005540005

Results and Publications

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