

Effect of a tomato sauce (OsteoCol) from vine-ripened tomatoes on lipids

Submission date 14/05/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/05/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/01/2021	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Intake of a tomato sauce with a high carotenoid (antioxidant) content in association with other lifestyle interventions may be a treatment for patients affected by common hypercholesterolemia (high blood cholesterol). Most studies focused on the benefits of lycopene, an antioxidant contained in tomato, on serum lipids but no studies have been specifically designed to assess the role of a tomato sauce from vine-ripened tomatoes (thus, naturally high in carotenoids) on patients affected by common hypercholesterolemia. The aim of this study is to investigate the effects of a tomato sauce from vine-ripened tomatoes on lipids and compare the effects with a well-known commercialized functional food with a lipid-lowering effect, a sterol-enriched yoghurt.

Who can participate?

Patients aged over 40 with polygenic hypercholesterolemia who are not taking medications or supplements

What does the study involve?

Participants are randomly allocated to consume either a functional tomato sauce or a sterol-enriched yoghurt every day for 6 weeks. Participants also receive oral and written recommendations to adhere to a Mediterranean dietary pattern, without energy restriction.

What are the possible benefits and risks of participating?

Participants receive continuous clinical support as well as cholesterol reduction with safe and natural methods. There are no risks of participating in the study because tomato sauce is obtained with natural methods and the yoghurt with sterols is already commercialised. If cholesterol increases, appropriate drugs are prescribed.

Where is the study run from?

University Magna Grecia (Italy)

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

September 2017 to May 2020

Who is funding the study?

1. University Magna Grecia Catanzaro (Italy)
2. Italian Society for the Study of Atherosclerosis (SISA) (Italy)

Who is the main contact?

1. Prof. Tiziana Montalcini
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2. Prof. Arturo Pujia
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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

06/2018/CE

Study information

Scientific Title

Effect of a novel functional tomato sauce (OsteoCol) from vine-ripened tomatoes on serum lipids in individuals with common hypercholesterolemia

Acronym

OsteoCol

Study objectives

Most studies focused on the benefits of lycopene on serum lipids but no studies have been specifically designed to assess the role of a tomato sauce from vine-ripened tomatoes on patients affected by polygenic hypercholesterolemia. This study will compare the lipid-lowering effect of this functional tomato sauce with a well-known commercialized functional food with a lipid-lowering effect, i.e. a sterol-enriched yoghurt.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 18/01/2018, 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: 06/2018/CE

Study design

Randomized cross-over study

Primary study design

Interventional

Secondary study design

Randomised cross over 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

Polygenic hypercholesterolemia

Interventions

Participants are randomised by simple randomization to:

1. A functional tomato sauce [namely OsteCol (registered Patent), from tomatoes ripened on-the-vine], 150 ml/day (by C.G. Food, SRL, Soverato, Italy)
2. A sterol-enriched yoghurt (100 g/die of Danacol, containing sterols 1.6 g/die, by Danone, SPA, Milano, Italy).

Participants will receive oral and written recommendations to adhere to a Mediterranean dietary pattern, without energy restriction. Macronutrient distribution as a percentage of total energy range from 50% to 55% carbohydrate, 15% to 20% protein and 20% to 35% fat, with a recommended protein intake of 1 g/kg of ideal body weight. Duration: 6 weeks.

Intervention Type

Other

Primary outcome measure

1. Total cholesterol measured by chemiluminescent immunoassay on COBAS 8000 (Roche, Switzerland), according to the manufacturer's instructions at baseline and 6 weeks
2. LDL-cholesterol calculated by the Friedewald formula at baseline and 6 weeks

Secondary outcome measures

LDL-cholesterol according with basal LDL-tertiles measured at baseline and 6 weeks

Overall study start date

01/09/2017

Completion date

30/05/2020

Eligibility

Key inclusion criteria

1. Individuals with polygenic hypercholesterolemia
2. Both genders
3. Aged over 40 years
4. Not taking medications or supplements

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

108

Total final enrolment

108

Key exclusion criteria

1. Familial hypercholesterolemia
2. Triglycerides concentration over 200 mg/dl
3. Secondary causes of hyperlipidemia
4. Debilitating diseases, as ascertained

Date of first enrolment

01/02/2018

Date of final enrolment

09/05/2018

Locations**Countries of recruitment**

Italy

Study participating centre

University Magna Grecia

viale S. Venuta

Catanzaro

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Sponsor information**Organisation**

University Magna Grecia Catanzaro

Sponsor details

Clinical Nutrition Unit

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Sponsor type

University/education

Website

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ROR

<https://ror.org/0530bdk91>

Funder(s)

Funder type

University/education

Funder Name

University Magna Grecia Catanzaro

Funder Name

Italian Society for the Study of Atherosclerosis (SISA)

Results and Publications

Publication and dissemination plan

The researchers will submit results in 2019/20 to scientific journals with an impact factor as well as popular magazines.

Intention to publish date

30/06/2020

Individual participant data (IPD) sharing plan

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

Type of data: Excel file.

When the data will become available: 30/05/2020.

For how long: currently not known.

Access criteria data will be shared including with whom, for what types of analyses: descriptive analysis of the population.

The researchers need to guarantee data anonymisation, all requests will be approved by the Principal Investigator.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	06/01/2021	12/01/2021	Yes	No