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

Submission date
14/05/2019

Recruitment status
No longer recruiting

Registration date
16/05/2019

Overall study status
Completed

Last Edited
12/01/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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@hot.mail.it; michelangelo.rossano@regione.calabria.it), ref: 06/2018/CE

Study design
Randomized cross-over study

Primary study design
Interventional

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
LDL-cholesterol according with basal LDL-tertiles measured at baseline and 6 weeks

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
University Magna Grecia Catanzaro

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes