

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

<b>Submission date</b> 14/05/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/05/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/01/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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  
tmontalcini@unicz.it
2. Prof. Arturo Pujia  
pujia@unicz.it

## Contact information

### Type(s)

Scientific

### Contact name

Prof Tiziana Montalcini

### Contact details

viale S.Venuta Università Magna Grecia  
Catanzaro  
Italy  
88100  
+39 (0)3316718386  
tmontalcini@unicz.it

### Type(s)

Scientific

### Contact name

Prof Arturo Pujia

### Contact details

viale S. Venuta  
Catanzaro  
Italy  
88100  
+39 (0)3316718206  
pujia@unicz.it

## 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@hotmail.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  
Catanzaro  
Italy  
88100

## 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?
<a href="#">Results article</a>	results	06/01/2021	12/01/2021	Yes	No