

# Effects of processing of tomato on bioavailability of phenolic compounds and inflammatory biomarkers related to atherosclerosis

<b>Submission date</b> 24/11/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/09/2019	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Bioavailability of phenolic compounds from tomato depending on its processing. Effects of processing of tomato on cellular and serum biomarkers related to atherosclerosis: An open randomized cross-over controlled trial.

### Acronym

Food Matrix Effect on Inflammatory Response

### Study objectives

Processing of tomato with and without olive oil will release the polyphenolic compounds from the complex matrix and increase their bioavailability. Thus, intake of processed tomato will reduce cellular and inflammatory biomarkers related to atherosclerosis. No adverse effects will be observed.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Institutional Review Board of the Hospital Clinic, Barcelona, Spain approved on the 9th November 2006 (ref: 2006/3351)

### Study design

Open randomised crossover controlled clinical trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Other

### Study type(s)

Other

### Participant information sheet

Written material on the protocol and the diet that should be followed by the subjects is administered at admission. Not available in web format, please use the contact details below to request a patient information sheet.

### Health condition(s) or problem(s) studied

Bioavailability and Atherosclerosis

### Interventions

Intervention 1: Administration of 7.14 g/kg of body weight of fresh tomato.

Intervention 2: Administration of 3.57 g/kg of body weight of tomato sauce cooked with refined olive oil.

Intervention 3: Administration of 3.57 g/kg of body weight of tomato sauce cooked without oil.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

1. Leukocyte adhesion molecule expression:

Peripheral lymphocyte and monocyte adhesion molecules on these cells will be marked with monoclonal antibodies (MAB) conjugated with fluorescein-isothiocyanate (FITC) and phycoerythrin (PE) by direct double immunofluorescence.

1.1. MAB used to mark adhesion molecules:

1.1.1. Anti-CD11a (LFA-1) (Bender MedSystems Diagnostics, Vienna)

1.1.2. Anti-CD40L (Bender MedSystems Diagnostics, Vienna)

1.1.3. Anti-CD11b (Mac-1) (Bender MedSystems Diagnostics, Vienna)

1.1.4. Anti-Syalil Lewis (anti-CD15s) (Pharmingen, San Diego, CA)

1.1.5. Anti-CD49d (VLA-4) (Cytogmos)

1.2. MAB used to mark T-lymphocytes: anti-CD2 (Caltag Laboratories, Burlingame, CA)

1.2. MAB used to mark monocytes: anti-CD14 (Caltag Laboratories, Burlingame, CA)

2. Soluble adhesion molecules:

The following serum soluble adhesion molecules (1-4) and other molecules (5-7) will be determined by enzyme-linked immunosorbent assay (ELISA) kits (Immunotech):

2.1. Soluble intercellular adhesion molecule-1 (sICAM-1)

2.2. Soluble vascular adhesion molecule 1 (sVCAM-1)

2.3. sE-selectin

2.4. sP-selectin

2.5. Soluble monocyte chemotactic protein-1 (sMCP-1)

2.6. Tumour necrosis factor-alpha (TNF-a)

2.7. Interleukin 1a (IL-1a)

3. Plasma and urine functional components study:

3.1. Plasma polyphenol concentration will be determined by Liquid Chromatography Tandem Mass Spectrometry (LC/MS/MS). The plasma polyphenol determinations will be carried out at 8 points during the 24h study, and urine polyphenol determinations at 0-6, 6-12 and 12-24 hours periods with the objective to obtain the plasma and urine phenolics kinetic and to investigate the different kinetic parameters used to evaluate their bioavailability; Area under the Curve (AUC), maximum concentration (Cmax), time to maximum plasma concentration (Tmax) and Time to maximum response (TMR).

3.2. Other studies to be carried out on the plasma and urine samples include:

3.2.1. Antioxidant capacity (Trolox-Equivalent Antioxidant Capacity [TEAC] assay, Oxygen Radical Absorbance Capacity [ORAC] assay)

3.2.2. Total phenolic concentration (Folin-Ciocalteu method)

3.2.3. Total Radical-trapping Antioxidant Parameter (TRAP) assay

3.2.4. Ferric Reducing Antioxidant Power (FRAP) assay

All variables (primary and secondary outcomes) will be measured at baseline and after each intervention.

## **Secondary outcome measures**

### **1. Medical record:**

1.1. A complete medical record will be obtained from all participants, which includes data on tomato intake, smoking and dietary habits.

1.2. Blood pressure and heart rate will be measured with an electronic apparatus Omron HEM-705CP (Netherlands).

### **2. Nutrition assessment and general analyses:**

2.1. All participants will complete a validated nutritional questionnaire at baseline to determine the total quantity of calories ingested in the previous month as well as the proportion corresponding to carbohydrates, lipids and proteins.

2.2. Overall nutrition will be determined by percentage of ideal weight, lean body mass and body mass index.

2.3. Waist perimeter will be measured.

2.4. The following measurements will also be obtained:

2.4.1. Red blood cell count

2.4.2. Haematocrit

2.4.3. Mean corpuscular volume

2.4.4. Leukocyte count

2.4.5. Glucose

2.4.6. Creatinine

2.4.7. Electrolytes

2.4.8. Uric acid

2.4.9. Transaminases

2.4.10. Lactate dehydrogenase

2.4.11. Alkaline phosphatase

2.4.12. Gamma-glutamyl transpeptidase

2.4.13. Bilirubin

### **3. Coagulation tests:**

3.1. Platelet count

3.2. Prothrombin time

3.3. Plasma fibrinogen

### **4. Serum lipoprotein levels and others**

4.1. Total cholesterol

4.2. Triglycerides

4.3. HDL cholesterol (cHDL)

4.4. cLDL

4.5. Apo A1

4.6. Apo B

### **5. Diet and exercise monitoring:**

Monitoring of the diet and physical exercise will be carried out before and after each intervention.

5.1. All participants will follow an isocaloric diet prepared according to their personal preferences. The diet will be strictly monitored during the study. Diet compliance will be assessed from 7-days diet records administered before each evaluation. The foods ingested will be converted into nutritional values with the aid of the Professional Diet Balancer software

(Cardinal Health Systems, Inc., Edina, MN).

5.2. Physical activity will also be evaluated with the Minnesota Leisure Time Physical Activity questionnaire which has also been validated in Spain.

All variables (primary and secondary outcomes) will be measured at baseline and after each intervention.

**Overall study start date**

03/11/2008

**Completion date**

31/12/2010

## **Eligibility**

**Key inclusion criteria**

Healthy adults (males and females)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

50

**Total final enrolment**

40

**Key exclusion criteria**

1. Previous history of cardiovascular disease (ischemic heart disease - angina or recent or old myocardial infarction, cerebral vascular accident, or peripheral vascular disease)
2. Homeostatic disorders
3. Any several chronic diseases
4. Hypertension or dislipemia
5. Smoking subjects
6. Alcoholism
7. Other toxic substance abuse

**Date of first enrolment**

03/11/2008

**Date of final enrolment**

31/12/2010

## **Locations**

## Countries of recruitment

Spain

## Study participating centre

Av. Joan XXIII s/n

Barcelona

Spain

08028

## Sponsor information

### Organisation

Spanish Ministry of Science and Innovation (Ministerio de Ciencia e Innovación [MICINN]) (Spain)

### Sponsor details

c/Albacete, 5

Madrid

Spain

28027

### Sponsor type

Government

### Website

<http://web.micinn.es/>

## Funder(s)

### Funder type

Government

### Funder Name

Spanish Ministry of Science and Innovation (Ministerio de Ciencia e Innovación [MICINN]) (Spain)  
(AGL2007-66638-C02-01/ALI)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	01/07/2016	17/09/2019	Yes	No