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

Submission date 24/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2010	**Overall study status** Completed	
Last Edited 17/09/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Protocol serial number
AGL2007-66638-C02-01/ALI

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

Study type(s)
Other

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(s)
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.

Key secondary outcome(s))

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.

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Healthy adults (males and females)

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Sex
All

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
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Sponsor information

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

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016	17/09/2019	Yes	No