

# Acute effects of coffee on endothelial function and glucose metabolism in healthy volunteers

**Submission date**  
31/10/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
06/11/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
04/06/2019

**Condition category**  
Nutritional, Metabolic, Endocrine

☐ Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
02/2007

## Study information

**Scientific Title**  
Acute effects of coffee on endothelial function and glucose metabolism in healthy volunteers

**Study objectives**  
Please note that as of 15/05/2008 this trial record was extensively amended. Most of the changes to this record can be found in the relevant field, under the date on which the

amendment was made. The following changes have also taken place:

1. The total number of participants has been amended from 20 to 50
2. Only 20 of the 50 participants were assessed for all primary and secondary outcome measures, whereas the remaining 30 participants were assessed only for the QTc intervals (secondary outcome field no. 3). Please see Primary/Secondary outcome measures field for detail.

Study hypothesis:

Caffeine or unknown components of coffee might acutely influence endothelial function as well as glucose metabolism.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from the Local Ethical Committee of the University Hospital of Palermo (I) on the 3rd October 2007 (ref: 09/07).

### **Study design**

Randomised, crossed, double-blind, placebo controlled study

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

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

Cardiovascular and metabolic diseases

### **Interventions**

Participants will receive on two occasions with a random and blind order respectively a cup of caffeinated coffee and a cup of decaffeinated coffee (a standardised cup of 25 ml Italian espresso) with a one week interval. The two beverages are obtained by the same mixture of coffee and they differ only for their caffeine content.

### **Intervention Type**

Drug

### **Phase**

Not Specified

### **Drug/device/biological/vaccine name(s)**

Caffeine

### **Primary outcome(s)**

Amendment as of 15/05/2008: Please note that the primary outcome measure was assessed in only 20 participants.

Acute effects of both coffees (caffeinated and decaffeinated) on endothelial function, measured as "Flow Mediated Dilation", and on glucose metabolism, as blood concentrations of glucose, insulin and c-peptide, will be measured in each occasion before, 30 and 60 minutes after coffee ingestion.

### **Key secondary outcome(s)**

Amendment as of 15/05/2008: Please note that all secondary outcome measures were assessed in only 20 participants, except the QTc interval measurement (no. 3 below), which was carried out for all participants.

1. Intra-renal haemodynamic measurements (resistance and pulsatility indexes), obtained before and 60 minutes after coffee ingestion in both occasions
2. Blood pressure, obtained before and 60 minutes after coffee ingestion in both occasions
3. Electrocardiogram with QTc interval measurement, obtained before and 60 minutes after coffee ingestion in both occasions
4. A blood sample will be collected before and 60 minutes after coffee ingestion in both occasions and the serum samples will be frozen at -80°C for measurement of some cytokines (Interleukin-6 [IL-6], Tumour Necrotising Factor [TNF]-alpha, etc.)

### **Completion date**

15/12/2007

## **Eligibility**

### **Key inclusion criteria**

1. Male and female healthy subjects
2. Range of age: 25 - 50 years
3. Range of Body Mass Index (BMI): 20 - 28 kg/m<sup>2</sup>

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

20

### **Key exclusion criteria**

1. Any metabolic, cardiovascular or systemic disease
2. Any drug treatment
3. Smoking habits
4. Pregnancy or lactation in the last six months

**Date of first enrolment**

01/10/2007

**Date of final enrolment**

15/12/2007

## Locations

**Countries of recruitment**

Italy

**Study participating centre**

Dipartimento di Medicina Interna, Malattie Cardiovascolari e Nefrourologiche

Palermo

Italy

90127

## Sponsor information

**Organisation**

University of Palermo (Italy)

**ROR**

<https://ror.org/044k9ta02>

## Funder(s)

**Funder type**

Government

**Funder Name**

Italian Ministry of the University of Scientific and Technological Research (Ministero Dell'università E Della Ricerca Scientifica E Tectnologica [MURST]) (Italy)

**Funder Name**

Coffee to be tested is offered by Morettino s.p.a. Palermo (Italy)

## 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?
<a href="#">Results article</a>	results	01/05/2010	04/06/2019	Yes	No