# Dose dependent acute effects of decaffeinated coffee on endothelial function and glucose metabolism in healthy volunteers

Submission date 09/05/2008	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 22/05/2008	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>[X] Results</li> </ul>
Last Edited 05/01/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<ul> <li>Individual participant data</li> </ul>

## Plain English summary of protocol

Not provided at time of registration

# **Contact information**

**Type(s)** Scientific

**Contact name** Dr Silvio Buscemi

### Contact details

Dipartimento di Medicina Interna, Malattie Cardiovascolari e Nefrourologiche Via del Vespro, 129 Palermo Italy 90127

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 01/2008

# Study information

Scientific Title

#### **Study objectives**

In a previous study (ISRCTN85096812 - http://www.controlled-trials.com/ISRCTN85096812) endothelial function and glucose metabolism improved after the ingestion of decaffeinated coffee therefore suggesting that non-caffeine components of coffee have beneficial effects. The hypothesis of this study is that these non-caffeine components of coffee might have dose dependent favourable effects on endothelial function and possibly on glucose metabolism.

**Ethics approval required** Old ethics approval format

#### Ethics approval(s)

Local Ethics Committee of the University Hospital of Palermo (I). Date of approval: 06/02/2008 (ref: 02/08)

**Study design** Randomised, cross-over, single-blind trial.

**Primary study design** Interventional

Secondary study design Randomised controlled trial

**Study setting(s)** Other

**Study type(s)** Not Specified

Participant information sheet

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

Cardiovascular and metabolic diseases/ clinical nutrition

#### Interventions

This is a cross-over, randomised trial.

Participants will receive, on two occasions in random order, one or two cups of decaffeinated coffee (a standardised cup of 25 ml Italian expresso) at one week interval.

Intervention Type Drug

**Phase** Not Specified

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

Coffee

#### Primary outcome measure

1. Fasting acute effects of the two different doses of coffee on endothelial function, measured as the flow mediated dilation (FMD). FMD measurements (outcome assessors blinded) will be performed before, 30 and 60 minutes after coffee ingestion.

2. Fasting acute effects of the two different doses of coffee on glucose metabolism, evaluated on the basis of blood concentrations of glucose, insulin and c-peptide. These blood measurements will be obtained before and 60 minutes after coffee ingestion.

#### Secondary outcome measures

1. Blood pressure, obtained before, 30 and 60 minutes after coffee ingestion

2. Heart rate, measured continuously for the entire duration of the test (60 min)

3. Electrocardiogram with QTc interval measurement, obtained before and 60 minutes after coffee ingestion

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 future measurements (Interleukin-6 [IL-6], tumour necrosis factor-alpha [TNF-alpha], etc.)

#### Overall study start date

01/04/2008

#### **Completion date**

15/06/2008

# 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^2

## Participant type(s)

Patient

#### Age group

Adult

Sex Both

**Target number of participants** 15

#### 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 01/04/2008

Date of final enrolment 15/06/2008

## 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)

**Sponsor details** Piazza Marina Palermo Italy 90100

**Sponsor type** University/education

Website http://www.unipa.it/

ROR https://ror.org/044k9ta02

# Funder(s)

**Funder type** Government

#### **Funder Name**

Ministry of Education and Research (Ministero dell'Università e della Ricerca - MURST) (Italy)

Alternative Name(s) Министерство образования и науки, Ministry of Education and Research, HM

**Funding Body Type** Government organisation

Funding Body Subtype National government

**Location** Estonia

**Funder Name** Association Onlus: Nutrition and Health (Associazione Onlus: Nutrizione e Salute) (Italy)

**Funder Name** The coffee to be tested is offered by A. Morettino s.p.a., Palermo (Italy)

## **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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2009		Yes	No