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

Submission date	Recruitment status	[_] Prospectively registered
31/10/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/11/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/06/2019	Nutritional, Metabolic, Endocrine	

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).

Primary study design
Interventional

Study design
Randomised, crossed, double-blind, placebo controlled study

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 expresso) 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^2

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?
Results article	results	01/05/2010	04/06/2019	Yes	No