

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

Submission date
09/05/2008

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
22/05/2008

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
05/01/2010

Condition category
Nutritional, Metabolic, Endocrine

☐ 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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Contact details

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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 espresso) 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/m²

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