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The short term effects of coffee and caffeine on the cardiovascular and autonomic nervous systems

Submission date	Recruitment status	[ ] Prospectively registered
17/05/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/08/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/11/2012	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The short term effects of coffee and caffeine on the cardiovascular and autonomic nervous systems: a crossover, double blind, placebo-controlled and cohort randomised clinical trial

Study objectives
Coffee and caffeine have/do not have an effect on the autonomic system as measured by changes of cardiac parameters and breathing frequency. This study uses two research models to investigate the short term effects (up to one hour) of coffee and caffeine preparations on the autonomic nerve system and recordings are made of cardiovascular parameters and breathing frequency.

The first model involves pre-test recording with post-test recording 30 and 60 minutes after administration. The second model uses continuous recordings for 45 minutes after administration of the test substance. Testing is carried out in supine, sitting and upright postures. The third and fourth models included physiological recordings.

Recordings undertaken:
1. Recording of cardiovascular parameters with Finometer-finger pulse contour measures providing measures of blood pressure, heart rate, ejection time, diastolic interval, dp/dt, diastolic pressure time index (DTPI), systolic pressure time index (SPTI), DPTI/SPTI, stroke volume, cardiac output, peripheral resistance, aortic impedance and arterial compliance
2. Recording of breathing frequency with Biopac Respiratory Effort Transducer (TSD201) attached to Finometer
3. R-R (heart beat) recordings with Nerve Express using a Polar thoracic band - used for determining heart rate variability measures

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the University of Westminster Ethics Committee on the 8th April 2004 (ref: 03/04-08)

Study design
Crossover, double blind, placebo-controlled, randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cardiovascular and autonomic nervous system functioning

Interventions
Each model was conducted over time and only one model was recruited for at a time. All models were crossover. Patients will be randomised to:
1. Placebo capsule
2. Caffeine capsule (67, 133, 200 mg)
3. Espresso coffee (16.5 mg caffeine)
4. Espresso coffee and caffeine/placebo capsule

The designs of the different models were as follows:

Model design 1:
Participants were monitored for 90s continuous recordings at 30 minutes and 60 minutes after intervention. The equipment is attached for 15 - 20 minutes each test period and between recording periods the equipment is removed. There are three recording periods per session: pre intervention and post intervention at 30 minutes and 60 minutes.

Model design 2:
Participants were monitored by a continuous recording which includes pre-intervention recording (baseline) and extends for 35 to 40 minutes after intervention. Continuous recordings of breathing and the cardiovascular system for approximately 45 minutes. The equipment is not removed from the participant during the experimental session. There is only one test period per session.

Model design 3:
Initially uncontrolled breathing, then alternating frequency (0.167 Hz/0.250 Hz). Recording for 270s in supine and upright postures.

Model design 4:
Recording for 270s with particpants engaging in four activities (lying, standing, cycling with heart rate: 115 bpm, cycling with heart rate: 135 bpm), presented in the same order for all participants.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Coffee, caffeine

Primary outcome measure
Pre-planned comparisons to placebo conditions:
1. The cardiovascular parameters derived from the Finometer recordings of the finger pulse

contour (www.finapres.com): systolic, diastolic and mean blood pressure, heart rate, ejection time, diastolic interval, dp/dt, DPTI, SPTI, DPTI/SPTI, ejection time, stroke volume, cardiac output, total peripheral resistance, aortic impedance and arterial compliance
2. Breathing rate

Timepoints:
Model 1: recording 30 and 60 minutes after intervention; test session 15 minutes
Model 2: constant recording for 40 minutes after intervention

Secondary outcome measures
1. Pre planned comparisons of intervention effects in different postures
2. Variability analysis of Finometer derived cardiovascular parameters as appropriate in a post experimental analysis
3. Dosage relationships

Timepoints:
Model 1: recording 30 and 60 minutes after intervention; test session 15 minutes
Model 2: constant recording for 40 minutes after intervention

Overall study start date
01/10/2004

Completion date
01/03/2009

Eligibility

Key inclusion criteria
1. Voluntary recruits from the students, staff and associates of the University of Westminster
2. Non-medicated
3. Normotensive
4. Aged 18 to 63 years, either sex
5. Habitual caffeine users (consumption of tea or coffee on a daily basis) or non caffeine users (less than 3 servings per week)

Model 4 only:
6. Regular cyclists

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

105 participants

Key exclusion criteria
1. Pregnant and breast feeding women
2. Hypertensive (blood pressure greater than 140/90 mmHg)
3. Users of prescribed medicines

For models 1 and 2:
4. Smokers

Date of first enrolment
01/10/2004

Date of final enrolment
01/03/2009

Locations

Countries of recruitment
Sweden

United Kingdom

Study participating centre
Box 65
Vaddo
Sweden
76040

Sponsor information

Organisation
University of Westminster (UK)

Sponsor details
c/o Dr Julie Whitehouse
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Sponsor type
University/education

Website
http://www.wmin.ac.uk/

ROR
https://ror.org/04ycpbx82

Funder(s)

Funder type
University/education

Funder Name
University of Westminster (UK) - PhD study (self-funded) at the School of Life Sciences

Funder Name
Donations received from:

Funder Name
Whitehorse Nutriceuticals (UK) - Dr Brian Whitton donated caffeine capsules,

Funder Name
Naturally Scientific (UK) - HPLC testing of caffeine levels in espresso coffees by Peter Whitton

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	01/04/2011		Yes	No

Results article	results	01/09/2012	Yes	No