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Caffeine, catecholamines and tremor

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/01/2015	Nervous System Diseases	[ ] Record updated in last year

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
N0265122314

Study information

Scientific Title
Caffeine, catecholamines and tremor

Study objectives
The study has 2 aims:
1. To investigate the short term effects of caffeine on tremor and relate them to other beta-2 mediated changes.
2. To investigate the nature of the tremor response to beta-2 agonists.
The generally accepted explanation for the tremorogenic effect of these drugs is that the twitch properties of the muscles are changed. The twitch becomes faster and the tetanic filsion frequency increases. As a consequence, for any likely rate of motor neuron firing the response of the muscle becomes more pulsatile. We will record tremor with a new isometric apparatus which allows this conclusion to be directly tested. Any component of the tremor which alternatively results from central activation can be distinguished by this new technique.
For information: Whairad HJ, Birmingham AT, MacDonald IA, Inch PJ, Mead JL. The influence of fasting and caffeine intake on finger tremor. European Journal of Clinical Pharmacology 1985:29; 37-43. See http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=4054205&query_hl=7&itool=pubmed_docsu

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Nervous System Diseases: Tremor

Interventions
Suitable volunteers will be seen prior to entry to the study. A full history and examination will be performed, including details of smoking, alcohol and caffeine intake. They will be given a written information sheet and a full explanation of the nature and purpose of the study. They will be asked to sign a consent form if they wish to take part.
The study will consist of five visits to the clinical investigation unit each separated by at least 72 hours from the preceding and following study day. Prior to each study day the volunteer will

abstain from caffeine containing foods and beverage for 48 hours and will not drink alcohol for the 24 hours preceding the investigation. Each visit will follow a standard protocol. The volunteer will attend and a cannula will be inserted into each ante-cubital fossa.
Baseline tremor and associated cutaneous electromyography (EMG), blood pressure and pulse rate will be measured using standard non-invasive techniques. Additionally a blood sample (to analyse for potassium, glucose and insulin concentrations) will be taker) prior to the volunteer receiving an oral dose of caffeine at 7mg/kg or placebo. 45 minutes after administration the volunteers' tremor, blood pressure and pulse rate will be measured and a blood sample taken. An infusion of the terbutaline (at either 2 or 7 µg/kg/minute or placebo (saline) at 35 ml/hour) intravenously infrised at the prescribed rate. The volunteers' tremor, blood pressure and pulse rate will be measured and a blood sample taken four more times at 15-minute intervals. The volunteer will then depart. This basic procedure will be repeated for each visit.

The volunteer will be required to attend five times in order to receive the following combinations:
An oral dose of caffeine at 7mg/kg with placebo infusion.
A placebo tablet with a terbutaline infusion of 2 µg/kg/hr set up and run for 45 minutes.
A placebo tablet with a terbutaline infusion of 7 µg/kg/hr set up and run for 45 minutes.
Caffeine at 7mg/kg plus Terbutaline infusion at 2 µg/kg/hr set up and run for 45 minutes.
Caffeine at 7mg/kg plus Terbutaline infusion at 7 µg/kg/hr set up and run for 45 minutes.
These different treatments will be performed in a randomized order.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Caffeine, terbutaline

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/03/2003

Completion date
16/03/2008

Eligibility

Key inclusion criteria
8 healthy volunteers aged 18-39 years of either sex will be recruited. They will each act as their own control. They will be taking no other medication (with the exception of the oral contraceptive pill).

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
39 Years

Sex
Both

Target number of participants
8

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
16/03/2003

Date of final enrolment
16/03/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Birmingham
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Birmingham NHS Trust (UK)

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