

# Caffeine, catecholamines and tremor

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|----------------------------------------|------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>30/09/2004   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>30/09/2004 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>27/01/2015       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                      | <input type="checkbox"/> Results                     |
|                                        |                                                      | <input type="checkbox"/> Individual participant data |
|                                        |                                                      | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Prof M J Kendall

### Contact details

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University of Birmingham  
Birmingham  
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## Additional identifiers

### Protocol serial number

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 tension 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](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

## **Primary study design**

Interventional

## **Study design**

Randomised controlled trial

## **Study type(s)**

Not Specified

## **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 taken 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 infused 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(s)**

Not provided at time of registration

### **Key secondary outcome(s)**

Not provided at time of registration

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Upper age limit**

39 Years

### **Sex**

All

**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**

United Kingdom

England

**Study participating centre**

University of Birmingham

Birmingham

United Kingdom

B15 2TT

**Sponsor information****Organisation**

Department of Health

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

University Hospital Birmingham NHS Trust (UK)

**Results and Publications**

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**  
Not provided at time of registration