ISRCTN37562266 https://doi.org/10.1186/ISRCTN37562266

The effects of Modafinil on functional magnetic resonance imaging (fMRI) brain activation and functional performance during visual stimulation and visually guided tracking manoeuvres after sleep deprivation

Submission date 24/02/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 13/04/2005	**Overall study status** Stopped	
Last Edited 16/09/2009	**Condition category** Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Robert J.O Davies

Contact details
Consultant in Respiratory Medicine
Oxford Centre for Respiratory Medicine
Churchill Hospital
Headington
Oxford
United Kingdom
OX3 7LJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
C03.056

Study information

Scientific Title

Acronym
Modafinil Study

Study objectives
Therefore we wish to examine brain activity and performance during hand/eye tracking manoeuvres, (as quantified by fMRI and our tracking tasks), in normal subjects before and after total sleep deprivation following treatment with Modafinil or placebo. We will compare whether the Modafinil has reversed the effects of the sleep deprivation, compared to placebo

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)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
N/A

Interventions
Please note that as of 16/09/09 the status of this trial has been changed to "Stopped" due to relocation of primary investigator (PI) and lack of funding.

Each subject will be scanned 3 times, the first as a baseline, after normal sleep, and then twice after sleep deprivation, following treatment with Modafinil or placebo, in random order. Within each scanning session the subject will perform a series of hand/eye tracking tests of varying difficulty in random order, and a global visual stimulation test. Following the scans objective sleepiness will be quantified from the OSLER test of subjective sleepiness and steering ability will be quantified from the Oxford Steering Simulator. Subjects will be pre-trained to stable performance on the tracking task prior to fMRI scanning.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Modafinil

Primary outcome measure
The primary endpoint of the trial is the difference in activation of the occipital visual cortex area responsible motion detection (V5/MT) during global visual stimulation after Modafinil and placebo

Secondary outcome measures
Sleep latency (measured by the OSLER test), driving simulator performance and tracking error will be secondary endpoints

Overall study start date
01/08/2004

Completion date
30/06/2006

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
30 Healthy volunteers between the ages of 18-65

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
30

Key exclusion criteria
Previous neurological disease

Date of first enrolment
01/08/2004

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Consultant in Respiratory Medicine
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details
University of Oxford (NDM)
Level 5, John Radcliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 9DU

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Industry

Funder Name
Cephalon UK Ltd (UK) (ref: Davies2004/unrestricted grant)

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