

Reversing the Effects of Sleep Deprivation (RESO)

Submission date 04/08/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 13/03/2018	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims?

Studies have repeatedly shown that modafinil, a drug that promotes alertness, is capable of reversing some of the effects of sleep deprivation. This study aim to assess the impact of modafinil on the thinking skills and hand-eye coordination of a small group of sleep deprived doctors.

Who can take part?

Male training grade doctors working within or affiliated to Imperial College Healthcare NHS Trust. Participants must be healthy and medication free. Specifically, individuals with a history of neurological illness, heart problems, breathing difficulties, substance misuse or psychiatric illness will not be eligible to take part.

What does the study involve?

All participants will undergo a period of skills training following which they will attend the study centre for one night of supervised sleep deprivation. Participants will be randomly allocated to receive either modafinil or placebo at 3am and will undergo a series of laboratory based tests of thinking and hand-eye coordination between 6am and approximately 8am. Doctors will be advised not to return to their clinical work for 48hrs following conclusion of the study.

What are the possible benefits and risks of taking part?

Participants can expect to learn basic technical skills relevant to surgical training. There are no other benefits to the participant from taking part in the study.

Possible side effects of modafinil include: neurological side effects such as headache and dizziness, cardiovascular side effects such as fast heart beat and palpitations, respiratory side effects such as cough and wheeze and gastrointestinal side effects such as dry mouth and bowel disturbance. A more detailed description of the drug and list of side effects is available at patient.co.uk: <http://www.patient.co.uk/medicine/Modafinil.htm>.

Where is the study run from?

The study will be run from Imperial College London, Department of Surgery and Cancer, St Mary's Hospital Campus.

When is the study starting and how long is it expected to run for?
August 2009 to March 2010

Who is funding the study?
Imperial College London, Department of Surgery and Cancer.

Who is the main contact?
Dr Colin Sugden (Academic Clinical Lecturer)
c.sugden@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Colin Sugden

Contact details
Imperial College London and Imperial College Healthcare NHS Trust
St Mary's Hospital
Praed Street
Paddington
London
United Kingdom
W2 1NY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
08/CD/008

Study information

Scientific Title
Can modulation of neurochemical pathways in the brain reverse the effects of sleep deprivation on the psychomotor and cognitive performance of surgical trainees?

Acronym
RESO

Study objectives

Modafinil is a well tolerated and effective pharmacological wakefulness promoting agent. We hypothesise that modafinil administration will improve the cognitive and clinical psychomotor performance of a cohort of acutely sleep deprived doctors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee, 22/06/2009, ref: 09/H0304/24

Study design

Randomised double blind placebo controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Neuropsychopharmacology, sleep deprivation, medical simulation

Interventions

1. Modafinil 200mg
2. Single administration per subject

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Modafinil

Primary outcome measure

1. Cognitive performance assessed using the Cambridge Neuropsychological Test Automated Battery (CANTAB) battery of neuropsychological tests
2. Clinical psychomotor performance assessed using the MIST-VR simulator

Secondary outcome measures

1. Subjective rating of fatigue - Stanford Scale and Visual Analogue Scale
2. Heart rate & blood pressure monitoring

Overall study start date

01/08/2009

Completion date

01/03/2010

Eligibility**Key inclusion criteria**

Healthy male resident doctors taking no regular medication and with experience of less than 10 laparoscopic cases as primary operator

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

40

Key exclusion criteria

1. History of psychiatric illness
2. Visual, auditory or motor impairment
3. Cardiac or neurological illness
4. Score of greater than 10 on the Epworth Sleepiness Scale
5. More than two positive responses to the CAGE questionnaire
6. History of drug or alcohol addiction
7. Consumption of more than eight cups of coffee per day

Date of first enrolment

01/08/2009

Date of final enrolment

01/03/2010

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Imperial College London and Imperial College Healthcare NHS Trust
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Imperial College London

Sponsor details
St Mary's Hospital
Praed Street
Paddington
London
England
United Kingdom
W2 1NY

Sponsor type
University/education

Website
<http://www3.imperial.ac.uk/>

ROR
<https://ror.org/041kmwe10>

Funder(s)

Funder type
University/education

Funder Name
Department of Surgery & Cancer, Imperial College London (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2012		Yes	No