ISRCTN44899331 https://doi.org/10.1186/ISRCTN44899331

Reversing the Effects of Sleep Deprivation (RESD)

Submission date	Recruitment status	[ ] Prospectively registered
04/08/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/08/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/03/2018	Mental and Behavioural Disorders	

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 form 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

Protocol serial number
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
RESD

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
1. Subjective rating of fatigue - Stanford Scale and Visual Analogue Scale
2. Heart rate & blood pressure monitoring

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
United Kingdom

England

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

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
University/education

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

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes