ISRCTN38764966 https://doi.org/10.1186/ISRCTN38764966

Effects of physostigimine and modafinil post brain injury

Submission date	Recruitment status	[ ] Prospectively registered
08/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
13/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/07/2016	Injury, Occupational Diseases, Poisoning	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
02/212

Study information

Scientific Title
Effects of physostigimine and modafinil post brain injury

Study objectives
Investigation of the effects of physostigmine and modafinil on cognitive function post brain injury

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridge Local Research Ethics Committee , 07/11/2002

Study design
Randomised 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 contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Severe head trauma, subarachnoid haemorrhage

Interventions
Patients are randomised to receive modafinil, physostigmine or placebo.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Cognitive changes noted on neuropsychology testing

Secondary outcome measures
Benefits noted on chronic therapy

Overall study start date
02/01/2004

Completion date
31/12/2010

Eligibility

Key inclusion criteria
Patients who have suffered brain injury

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
Past history of psychiatric illness

Date of first enrolment
02/01/2004

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Divison of Anaesthesia
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Addenbrookes NHS Trust Hospital + Cambridge University (UK)

Sponsor details
c/o Claudia Rizzini
R&D Department
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/055vbxf86

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Addenbrookes Hospital (UK) - Division of Anaesthesia

Funder Name
Medical Research Council (MRC) (UK) - Partially funded by MRC Grant No G9439390 ID 65883

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