

Effects of physostigmine and modafinil post brain injury

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
02/212

Study information

Scientific Title
Effects of physostigmine 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

Primary study design

Interventional

Study design

Randomised placebo controlled trial

Study type(s)

Treatment

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(s)

Cognitive changes noted on neuropsychology testing

Key secondary outcome(s)

Benefits noted on chronic therapy

Completion date

31/12/2010

Eligibility

Key inclusion criteria

Patients who have suffered brain injury

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre**Divison of Anaesthesia**

Cambridge

United Kingdom

CB2 2QQ

Sponsor information**Organisation**

Addenbrookes NHS Trust Hospital + Cambridge University (UK)

ROR

<https://ror.org/055vbx86>

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration