# Effects of physostigimine and modafinil post brain injury

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

Prof David Menon

#### Contact details

Divison of Anaesthesia University of Cambridge Addenbrookes Hospital Cambridge United Kingdom CB2 2QQ

## Additional identifiers

Protocol serial number 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

#### 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/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**

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?

Participant information sheet 11/11/2025 No Yes