

# Effects of physostigimine and modafinil post brain injury

<b>Submission date</b> 08/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 13/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/07/2016	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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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**Contact details**  
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## 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/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