Effect of methylphenidate on neural mechanisms underlying attention deficit after closed head injury

Submission date	Recruitment status	Prospectively registered
12/09/2003	No longer recruiting	∐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	☐ Results
Last Edited	Condition category	Individual participant data
25/05/2016	Mental and Behavioural Disorders	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

N0234108360

Study information

Scientific Title

Effect of methylphenidate on neural mechanisms underlying attention deficit after closed head injury

Study objectives

Do event-related potentials provide objective markers to monitor drug effects in ameliorating attention deficits after closed head injury?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised double-blind placebo controlled crossover group open trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Attention deficit after closed head injury

Interventions

Double-blind, placebo controlled, crossover design and open trials (pilot study).

The study is aimed to evaluate the effectiveness of a neurophysiological method, Event-related brain potentials (ERPs), for monitoring the action of methylphenidate in normalising attention deficits after closed head injury. The drug will be administered in a prospective, two-group, randomised, double-blind, placebo-controlled, crossover design. Forty subjects who sustained a closed head injury will be examined in three occasions: a drug-free baseline session and after a counterbalanced treatment of 6 weeks course each of methylphenidate and placebo (lactose). Treatments will be separated by 1 week of wash-out to minimise carryover effects of medication. Drugs will be given orally. The dose of methylphenidate/placebo will start at 20 mg/day and will increase until reaching clinical effectiveness, up to 60 mg/day. Each examination will consist in the recording of a set of ERPs associated with attention function, from the scalp. Traditional behavioural and neuropsychological measures of attention will be also obtained from each patient.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Methylphenidate

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date

30/04/2006

Eligibility

Key inclusion criteria

Closed head injured patients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Current history of neurological and/or psychiatric disorders
- 2. History of movement disorders
- 3. Epilepsy
- 4. Current use of MAO inhibitors or coumarin anticoagulants
- 5. Drug abuse
- 6. Problems of galactose intolerance
- 7. The Lapp lactase deficiency or glusoce-galactose malabsorption
- 8. Severe hypertension
- 9. Cardiac arrhythmia
- 10. Angina pectoris
- 11. Hyperthyroidism
- 12. Glaucoma
- 13. Thyrotoxicosis
- 14. Pregnancy
- 15. Severe hand motor deficit

Date of first enrolment

01/05/2003

Date of final enrolment

30/04/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Burden Neurological Institute
Bristol
United Kingdom
BS16 1JB

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Charity

Funder Name

The Big Lottery Fund (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration