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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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2003

Completion date
30/04/2006

Eligibility

Key inclusion criteria
Closed head injured patients

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type
Charity

Funder Name
The Big Lottery Fund (UK)

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