ISRCTN27103516 https://doi.org/10.1186/ISRCTN27103516

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
Dr Dolores Polo

Contact details
Burden Neurological Institute
North Bristol NHS Trust
Frenchay Hospital
Frenchay
Bristol
United Kingdom
BS16 1JB
+44 (0)117 918 6723
dolorespolo@hotmail.com

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

Primary study design
Interventional

Study design
Randomised double-blind placebo controlled crossover group open trial

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