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A Randomised Controlled Trial of the effects of donepezil on cognitive, behavioural, and functional outcome in traumatic brain injury

Submission date
18/11/2005

Recruitment status
No longer recruiting

Registration date
18/11/2005

Overall study status
Completed

Last Edited
17/08/2009

Condition category
Injury, Occupational Diseases, Poisoning

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

MCT-58345

Study information

Scientific Title

Study objectives
1. To demonstrate if an acetylcholinesterase inhibitor, donepezil, will improve cognition, affect, behavioural, functional and quality of life outcomes in patients with a history of TBI
2. To identify predictors of positive response to acetylcholinesterase inhibitors in this population
3. To increase understanding of basic neuronal mechanisms underlying human cognition and behaviour

Ethics approval required
Old ethics approval format

Ethics approval(s)
The joint Baycrest Centre for Geriatric Care/University of Toronto Research Ethics and Scientific Review Committee, Toronto, ON, January 16, 2003

Study design
Randomised placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Traumatic Brain Injury (TBI)

Interventions
Acetylcholinesterase inhibitor donepezil versus placebo for six months

Trial details received 12 Sept 2005

Intervention Type
Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Donepezil

Primary outcome measure
Episodic verbal learning and memory measured at six months.

Secondary outcome measures
1. Information processing speed at two and six months
2. Attention at two and six months
3. Problem solving at two and six months
4. Behaviour at two and six months
5. Affect at two and six months
6. Daily functioning at two and six months
7. Quality of life at two and six months

Overall study start date
01/06/2004

Completion date
30/06/2006

Eligibility

Key inclusion criteria
1. History of head trauma resulting from contact forces or an acceleration/deceleration event
2. Aged 18 - 55 years, either sex
3. At least 6 months post injury
4. Cognitive complaints or cognitive impairment as assessed by the treating clinician
5. Objective evidence of cognitive impairment in the realm of attention, memory, or executive functioning
6. Outpatient status
7. Able to identify a caregiver
8. Consent granted by subjects NOT deemed incompetent to do so OR consent given by substitute decision maker to participate in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. History of other central nervous system injury or disease (e.g. Alzheimers disease)
2. Relative contradictions for donepezil (including uncontrolled diabetes, current peptic ulcer, glaucoma etc.)
3. History of ongoing alcohol or drug abuse
4. Current Diagnostic and Statistical Manual of Mental Disorders, fourth edition (DSM-IV) axis I diagnosis of schizophrenia, bipolar disorder, or untreated depression
5. Physical or language impediments to completion of the measures
6. Concurrent of benzodiazepines, all antidepressants (with the exception of selective serotonin re-uptake inhibitors [SSRIs], which will be allowed), neuroleptics, and/or anticholinergic medications
7. Persistent post traumatic amnesia, as defined by a Galveston orientation and amnesia test (GOAT) score of 75 or less at the time of study
8. Age <18 or Age >55
9. Not in agreement to use acceptable contraception
10. Performance below 9 on the forced-choice component of the 21 item test
11. Performance of 85 or above (index score) in each construct of the RBANS test

Date of first enrolment
01/06/2004

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
Canada

Study participating centre
Baycrest Centre for Geriatric Care
Toronto
Canada
M6A 2E1

Sponsor information

Organisation
Baycrest Centre for Geriatric Care (Canada)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03gp5b411

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-58345)

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