

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	<input type="checkbox"/> Prospectively registered
Registration date 18/11/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/08/2009	Condition category 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

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

Study type(s)

Treatment

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(s)

Episodic verbal learning and memory measured at six months.

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration