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Oestrogen trial to delay the onset of memory impairment

Submission date	Recruitment status	[ ] Prospectively registered
01/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/05/2009	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
MCT-15222

Study information

Scientific Title
A randomised double-blind trial of the effects of hormone therapy on delayed verbal recall in older women

Study objectives

To examine the effectiveness of hormone replacement therapy (HRT) in memory-impaired women at risk for probable Alzheimer's disease (AD).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunnybrook and Women's College Health Sciences Centre Research Ethics Board (REB) approved on the 26th June 2003

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Alzheimers disease (AD)

Interventions
Oestradiol and norethindrone versus placebo.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Oestradiol, norethindrone

Primary outcome(s)
1. Alzheimer Disease Assessment Scale - cognitive subtest (ADAS-COG) at 1 and 2 years
2. % of cases with emergent Alzheimer's disease

Key secondary outcome(s))
1. Pharmacoeconomic analysis
2. Quality of life
3. Neuropsychological test performance

Completion date
30/04/2006

Eligibility

Key inclusion criteria

1. History of myocardial infarction, bypass surgery, angioplasty or unstable angina for more than one year
2. Admitted after approval from family physician
3. Non-demented memo-impaired women who are at a greater than or equal to 50% probability of developing AD

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Diagnosis of a dementing disorder, including AD
2. History of any conditions that might affect cognitive functioning, e.g., chronic alcohol or drug abuse, stroke, hypoxia, intracranial mass lesions, psychoses, brain trauma, or other neurological diseases
3. A medical condition with a probable prognosis of death less than two years or any unstable medical condition, including active hepatic dysfunction or disease
4. Conditions that might be exacerbated by oestrogen, including history of breast cancer, endometrial cancer, abnormal mammogram, abnormal pelvic ultrasound
5. Congestive heart failure (New York Heart Association [NYHA] Class III and IV)
6. History of myocardial infarction, bypass surgery, angioplasty or unstable angina within the past year
7. Current or history of thromboembolic event
8. Use of donepezil, galantamine, rivastigmine or hydergine less than two weeks before initiation of oestrogen therapy
9. Past use of any mode or dose of hormone replacement therapy for duration longer than half the period of time that it was used
10. 0.50 probability of developing AD in two years based on performance on the API
11. Less than 60 years of age
12. Not fluent in English
13. Perception: cant read normal print with or with out glasses or cant hear normal speech with or with out hearing aid
14. Current use of selective oestrogen receptor modulators

Date of first enrolment
01/01/1998

Date of final enrolment
30/04/2006

Locations

Countries of recruitment
Canada

Study participating centre
A145 Geriatric Research Unit
Toronto, Ontario
Canada
M4N 3M5

Sponsor information

Organisation
Sunnybrook and Women's College Health Sciences Centre (Canada)

ROR
https://ror.org/03wefcv03

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-15222)

Funder Name
Shire Biochem Inc. (Canada)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2009		Yes	No