# Oestrogen trial to delay the onset of memory impairment

Submission date	Recruitment status  No longer recruiting	Prospectively registered	
01/09/2005		☐ Protocol	
<b>Registration date</b> 01/09/2005	Overall study status Completed	Statistical analysis plan	
		[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

Dr Mary Catherine Tierney

#### Contact details

A145 Geriatric Research Unit 2075 Bayview Avenue Sunnybrook & Women's College HS Centre Toronto, Ontario Canada M4N 3M5

# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

# Study type(s)

Treatment

#### Participant information sheet

# 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 measure

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

#### Secondary outcome measures

- 1. Pharmacoeconomic analysis
- 2. Quality of life
- 3. Neuropsychological test performance

#### Overall study start date

01/01/1998

#### 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

#### Age group

Adult

#### Sex

Both

#### Target number of participants

146

#### 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)

## Sponsor details

University of Toronto 2075 Bayview Avenue Toronto Canada M4N 3M5

#### Sponsor type

Not defined

#### Website

http://www.sunnybrook.ca/

#### **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**

# 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

# **Study outputs**

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