ISRCTN55070842 https://doi.org/10.1186/ISRCTN55070842

# Effects of estradiol on cognitive function in elderly men with mild cognitive impairment

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 18/11/2005 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 14/12/2005 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 21/09/2007 | 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

# Study information

### Scientific Title

### Study objectives
The hypothesis was that oral micronised estradiol (1 mg once a day [QD]) taken for three months would produce symptomatic improvement in memory in men with mild cognitive impairment, as compared to placebo.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval received on the 16th November 2000 (ref: 99-061).

### Study design
Intreventional - randomised, double-blind, placebo-controlled, cross-over design.

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Mild cognitive impairment

### Interventions
Comparing the results of participants on three months of estradiol versus three months on placebo.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Estradiol

### Primary outcome measure

1. Mini-Mental Status Exam (MMSE)
2. Alzheimer's Disease Assessment Scale (ADAS)
3. Neuropsychatric Inventory (NPI)
4. Clinicial impression based on interview (CIBIC)

### Secondary outcome measures
Blood test results.

### Overall study start date
01/11/1999

### Completion date
30/07/2004

## Eligibility

### Key inclusion criteria
1. Male with mild cognitive impairment (Mini-Mental State Examination [MMSE] of 26 to 30)
2. Between the ages of 55 to 98
3. Hypertension was well controlled
4. Had a caregiver

### Participant type(s)
Patient

### Age group
Adult

### Sex
Male

### Target number of participants
40 men with mild cognitive impairment

### Key exclusion criteria
1. Carcinoma of the prostate, hypercalcaemia, metabolic diseases, severe Chronic Obstuctive Pulmonary Disease (COPD) and renal insufficiency
2. Clotting abnormality, hyper-coagulable states, sleep apnoea
3. Patients on coumadin with Deep Vein Thrombosis (DVT) (or with a known clotting disorder) and diabetes (if uncontrolled)
4. Liver disease, unstable coronary artery disease, history of cerebrovascular accident, recent classical migraines, thrombophlebitis or thromboembolic disease
5. Must not be on any other cognitive enhancing treatment. If so, must be washed-out for 30 days

### Date of first enrolment
01/11/1999

### Date of final enrolment
30/07/2004

# Locations

### Countries of recruitment
Canada

United States of America

### Study participating centre
**Jewish General Hospital**
Montreal, PQ
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# Sponsor information

### Organisation
Institute for the Study of Aging (USA)

### Sponsor details
767 Fifth Avenue, Suite 4600
New York City, NY
United States of America
10153
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tlee@rslmgmt.com

### Sponsor type
Research organisation

### ROR
https://ror.org/049v75w11

# Funder(s)

### Funder type
Charity

### Funder Name
Institute for the Study of Aging (ISOA) (USA)

# 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