

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

<b>Submission date</b> 18/11/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 14/12/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/09/2007	<b>Condition category</b> Mental and Behavioural Disorders	<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

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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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

### **Key secondary outcome(s)**

Blood test results.

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**Key exclusion criteria**

1. Carcinoma of the prostate, hypercalcaemia, metabolic diseases, severe Chronic Obstructive 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

Canada

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# Sponsor information

## Organisation

Institute for the Study of Aging (USA)

## ROR

<https://ror.org/049v75w11>

# Funder(s)

## Funder type

Charity

## Funder Name

Institute for the Study of Aging (ISOA) (USA)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration