

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

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

Contact name

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Additional identifiers

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).

Primary study design

Interventional

Study design

Interventional - randomised, double-blind, placebo-controlled, cross-over design.

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. Clinical 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

H3T 1E2

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