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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

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. Neuropsychatric 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 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
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