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

Contact name

Dr Howard Chertkow

Contact details

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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 Canada H3T 1E2

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 +1 212 572 4116 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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration