

Testosterone, aging and cognitive functioning

Submission date 28/02/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/10/2008	Condition category Pregnancy and Childbirth	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

A300413; NTR404

Study information

Scientific Title

Acronym

OLDER

Study objectives

Recent research showed a correlation between age related changes in hormone levels and cognitive decline and the emergence of Alzheimer disease in both men and women. Most research however is conducted in women.

The aim of this study is to further investigate the relation between testosterone level and cognitive functioning in older men. In order to determine testosterone level, total-, sex hormone-binding globulin (SHBG)- and albumin bound and bioavailable testosterone will be measured.

Hypothesis:

Serum testosterone levels in men will be related to basic cognitive functions, such as mental processing speed and cognitive control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local ethics committee (Medisch Ethische Toetsings Commissie Erasmus MC) on the 28th February 2005 (ref: 2005-071).

Study design

Non-randomised, non-controlled, clinical trial

Primary study design

Interventional

Secondary study design

Single-centre

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Benign prostatic hyperplasia (BPH), fertility problems

Interventions

Three cognitive computer tests are aimed to measure basal information processing speed, ability to suppress irrelevant stimuli and visuospatial perception, respectively.

Two out-patient groups will be included:

1. BPH-patients in the age of 55 to 75, and
2. Patients with fertility symptoms in the age of 20 to 45 years

Please note that this study was closed on the 19th February 2007.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

We expect a correlation between serum level testosterone and basic cognitive functions such as cognitive speed and cognitive control.

Secondary outcome measures

The relative contributions of age and testosterone level to cognitive functions will be established.

Overall study start date

21/03/2005

Completion date

01/03/2007

Eligibility

Key inclusion criteria

1. Age between 55 and 75 or age between 20 and 45
2. Urological complaints suspected to be benign prostatic hyperplasia (BPH) or fertility symptoms
3. Subjective healthy impression

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

200

Key exclusion criteria

Does not comply with the above inclusion criteria

Date of first enrolment

21/03/2005

Date of final enrolment

01/03/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Erasmus Univeristy Rotterdam

Rotterdam

Netherlands

3000 DR

Sponsor information

Organisation

Erasmus Medical Centre (The Netherlands)

Sponsor details

Department of Urology

P.O. Box 1738

Rotterdam

Netherlands

3000 RD

Sponsor type

Hospital/treatment centre

Website

<http://www.erasmusmc.nl/>

ROR

<https://ror.org/018906e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Erasmus Medical Centre (The Netherlands)

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