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# The Effects of Long term testosterone supplementation In testosterone deficient men on Quality of life, Sarcopenia, cognitive function, Obesity and vasculaR ageing

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 16/05/2005 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 16/05/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 27/10/2022 | Urological and Genital Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

### ClinicalTrials.gov number

### Secondary identifying numbers
NTR31

# Study information

### Scientific Title
The effects of testosterone supplementation on functional mobility, quality of life, body composition, cognitive function, aortic stiffness and cardiovascular risk factors, and bone mineral density in ageing men with an age-related decline of testosterone

### Acronym
The ELIQSOR study

### Study objectives
Serum testosterone levels decline gradually after the age of 50 years. This decline coincides with increasing signs and symptoms of aging, including tiredness and lack of energy, diminished libido, erectile dysfunction, reduced muscle mass and strength, reduced bone density, depression and diminished well-being. Androgen replacement might have a beneficial influence on these organs and functions in the aging male, but there are only limited clinical data available on the effects of testosterone replacement in males with a age-related decline of testosterone. Moreover, the results of this data are conflicting, insignificant or the study design has been insufficient.

Therefore, we conducted this randomised, placebo-controlled trial to assess the effects of testosterone supplementation on functional mobility, quality of life, body composition, cognitive function, aortic stiffness and cardiovascular risk factors, bone mineral density and safety (prostate, liver enzymes, haematological parameters) in ageing men with an age-related decline of testosterone.

The hypothesis is that testosterone supplementation improves functional mobility, quality of life, body composition, cognitive function, aortic stiffness and cardiovascular risk factors, and bone mineral density compared to placebo.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
The Institutional Review Board of the University Medical Center Utrecht approved the study protocol.

### Study design
Randomised, placebo controlled, parallel group, double blinded trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Age-related decline of testosterone

### Interventions
Four capsules of 40 mg testosterone undecanoate (TU) or placebo will be administered daily for 26 weeks.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Testosterone

### Primary outcome measure
Functional mobility and quality of life.

### Secondary outcome measures
1. Body composition
2. Cognitive function
3. Aortic stiffness and cardiovascular risk factors
4. Bone mineral density and safety (prostate, liver enzymes and haematological parameters)

### Overall study start date
01/01/2004

### Completion date
01/04/2005

## Eligibility

### Key inclusion criteria
1. Men with testosterone level below the 50th percentile cut-off point (study population-based testosterone distribution)
2. Age more than 60 years

### Participant type(s)
Patient

### Age group

Senior

### Sex
Male

### Target number of participants
240

### Key exclusion criteria
1. Severe diseases or conditions interfering with conduct of study
2. Conditions for which increase of androgen-like substances are contra-indicated
3. Symptomatic prostate hypertrophy, serious renal and liver function disturbances, heart failure, prostate or breast cancer
4. Diabetes mellitus de novo or already treated. A fasting capillary glucose level of 6.9 mmol/l or higher.
5. Diseases of adrenal gland, hypothalamo-pituitary-adrenal or -gonadal axis
6. Use of steroids or androgens six months before study

### Date of first enrolment
01/01/2004

### Date of final enrolment
01/04/2005

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Julius Centrum**
Utrecht
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3508 BA

## Sponsor information

### Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

### Sponsor details
Department of Geriatrics
P.O. Box 85500

Utrecht
Netherlands
3508 GA

### Sponsor type
University/education

### Website
http://www.umcutrecht.nl/zorg/

### ROR
https://ror.org/04pp8hn57

## Funder(s)

### Funder type
Research organisation

### Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (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
Not provided at time of registration

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | Protocol | 03/08/2006 | | Yes | No |
| Results article | | 01/12/2007 | | Yes | No |
| Results article | | 02/01/2008 | | Yes | No |