

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

<b>Submission date</b> 16/05/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/05/2005	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 27/10/2022	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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

Netherlands

3508 BA

## **Sponsor information**

**Organisation**

University Medical Centre Utrecht (UMCU) (The Netherlands)

**Sponsor details**

Department of Geriatrics

P.O. Box 85500

Utrecht  
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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?
<a href="#">Protocol article</a>	Protocol	03/08/2006		Yes	No
<a href="#">Results article</a>		01/12/2007		Yes	No
<a href="#">Results article</a>		02/01/2008		Yes	No