

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

Submission date 16/05/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 16/05/2005	Overall study status Completed	☒ Protocol
Last Edited 27/10/2022	Condition category Urological and Genital Diseases	☐ Statistical analysis plan
		☒ Results
		☐ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

Functional mobility and quality of life.

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Male

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)

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

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?
Results article		01/12/2007		Yes	No
Results article		02/01/2008		Yes	No
Protocol article	Protocol	03/08/2006		Yes	No