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.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21427

Source
Nationaal Trial Register

Brief title
The ELIQSOR study (The Effects of Long term testosterone supplementation In testosterone deficient men on Quality of life, Sarcopenia, cognitive function, Obesity and vasculaR ageing).

Intervention

Outcome measures

Primary outcome

Functional Mobility and Quality of Life.

Secondary outcome

Body Composition, Cognitive Function, Aortic Stiffness and Cardiovascular Risk Factors, Bone Mineral Density and Safety (Prostate, Liver Enzymes and Haematological Parameters).

Study description

Background summary

Serum testosterone levels decline gradually after the age of 50 year. This decline coincides with increasing sigh and symptoms of aging, including tiredness and lack of energy, diminished libido, erectily 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 randomized, 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, hematological parameters) in ageing men with an age-related decline of testosterone.

Study objective

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.

Study design

N/A

Intervention

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

Contacts

Public
University Medical Center Utrecht (UMCU), Julius Centrum,
P.O. Box 85500

Marielle H. Emmelot-Vonk
Utrecht 3508 GA
The Netherlands
+31 (0)30 2509291
Scientific
University Medical Center Utrecht (UMCU), Julius Centrum,
P.O. Box 85500
Marielle H. Emmelot-Vonk
Utrecht 3508 GA
The Netherlands
+31 (0)30 2509291

Eligibility criteria

Inclusion criteria

Men with testosterone level below the 50th percentile cut-of point (study population-based testosterone distribution) and age > 60 years.

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 6 months before study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2004
Enrollment:	240
Type:	Actual

Ethics review

Positive opinion

Date:	14-12-2004
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7

Register	ID
NTR-old	NTR31
Other	: 014-91-063 (NWO)
ISRCTN	ISRCTN23688581

Study results

Summary results
JAMA. 2008 Jan 2;299(1):39-52.