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.

Gepubliceerd: 14-12-2004 Laatst bijgewerkt: 13-12-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21427

Bron
NTR

Verkorte titel
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).

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Functional Mobility and Quality of Life.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2004
Aantal proefpersonen:	240
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-12-2004
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7
NTR-old	NTR31
Ander register	: 014-91-063 (NWO)
ISRCTN	ISRCTN23688581

Resultaten

Samenvatting resultaten
JAMA. 2008 Jan 2;299(1):39-52.