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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

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.

Primary study design
Interventional

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

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