ISRCTN07197979 https://doi.org/10.1186/ISRCTN07197979

Testosterone Replacement in Diabetes Mellitus with Vascular Disease

Submission date	Recruitment status
28/09/2007	No longer recruiting
Registration date	**Overall study status**
28/09/2007	Completed
Last Edited	**Condition category**
18/04/2012	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr TH Jones

Contact details
Medicine
Barnsley District General Hospital NHS Trust
Gawber Road
Barnsley
United Kingdom
S75 2EP

Additional identifiers

Protocol serial number
N0034170256

Study information

Scientific Title

Study objectives

To the effect of 12 weeks of testosterone replacement, given as testosterone esters 200mg from Sustanon 250 IM injection, on arterial stiffness measured by ultrasound derived stiffness index B of the femoral artery in men with a combination of Diabetes Mellitus, Peripheral Vascular Disease and hypogonadism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Single centre randomised double blind placebo controlled parallel study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Diabetes

Interventions
Sustanon vs placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sustanon

Primary outcome(s)
The effectiveness of 12 weeks of testosterone replacement, given as testosterone esters 200mg from Sustanon 250 IM injection, on arterial stiffness measured by ultrasound derived stiffness index B of the femoral artery in men with a combination of Diabetes Mellitus, PVD and hypogonadism.

Key secondary outcome(s)
The effects of testosterone on Glycated Haemoglobin.

Completion date
01/06/2006

Eligibility

Key inclusion criteria
1. Men with Diabetes M, hypogonadism and PVD
2. Older than 40 years old
3.Type 2 Diabetes Mellitus treated with insulin with or without oral hypoglycaemics
4. Serum testosterone less than 12mmol/L on two consecutive morning samples taken on different days
5. Symptoms attributable to hypogonadism in the opinion of the investigator
6. Agreement to maintain, diabetic antihypertensive and antilipid treatments at prior doses for the duration of the study
7. Ability to give written informed consent and verbal and written explanation in the English language
8. Ability to comply with all study requirements

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Current or previous breast cancer
2. Current or previous prostate cancer
3. Raised prostate specific antigen (PSA) or abnormal digital rectal examination suspicious of prostate cancer unless diagnosis excluded after specialist urology opinion and/or prostate biopsy
4. Severe symptoms of benign prostatic hypertrophy (prostatism)
5. Treatment with testosterone in the 3 months prior to the trial.
6. Investigational drug treatment in the 3 months prior to the trial
7. Any other reason considered significant by the investigators at the time of assessment

Date of first enrolment
01/10/2005

Date of final enrolment
01/06/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Medicine
Barnsley
United Kingdom
S75 2EP

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Barnsley Hospital NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

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	results	01/05/2007		Yes	No