

Testosterone Replacement in Diabetes Mellitus with Vascular Disease

Submission date

28/09/2007

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

28/09/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

18/04/2012

Condition category

Nutritional, Metabolic, Endocrine

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Single centre randomised double blind placebo controlled parallel study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

The effects of testosterone on Glycated Haemoglobin.

Overall study start date

01/10/2005

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

Age group

Adult

Sex

Male

Target number of participants

30

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

England

United Kingdom

Study participating centre**Medicine**

Barnsley

United Kingdom

S75 2EP

Sponsor information

Organisation

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Barnsley Hospital NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**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