

# 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**  
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**Contact details**  
Medicine  
Barnsley District General Hospital NHS Trust  
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## 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?
<a href="#">Results article</a>	results	01/05/2007		Yes	No