

# Effect of Testosterone replacement on glycaemic control and insulin sensitivity in hypogonadal men with type 2 diabetes

**Submission date**  
30/09/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
30/09/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
12/11/2008

**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

N0034128967

# Study information

## Scientific Title

### Study objectives

To assess the effect of testosterone on glycaemic control and insulin sensitivity in type 2 diabetic men with hypogonadism.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

## Participant information sheet

### Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Hypogonadism

### Interventions

Testosterone replacement vs placebo

### Intervention Type

Drug

### Phase

Not Specified

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

Testosterone

### Primary outcome measure

Efficacy of testosterone replacement

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/02/2003

**Completion date**

31/07/2004

## Eligibility

**Key inclusion criteria**

Diabetic men above 30 yrs old with hypogonadism

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Male

**Target number of participants**

20 male patients

**Key exclusion criteria**

Hormone manipulating therapy, inflammatory disease, infection, prostate carcinoma, elevated PSA

**Date of first enrolment**

01/02/2003

**Date of final enrolment**

31/07/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Medicine

Barnsley

United Kingdom

S75 2EP

# Sponsor information

## Organisation

Department of Health

## Sponsor details

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), BDGH Small Projects Fund (internal funding)

# 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	01/06/2006		Yes	No