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

Submission date	Recruitment status	Prospectively registered		
30/09/2005	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/09/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
12/11/2008	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr TH Jones

Contact details

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Additional identifiers

Protocol serial number 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

Study type(s)

Not Specified

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(s)

Efficacy of testosterone replacement

Key secondary outcome(s))

Not provided at time of registration

Completion date

31/07/2004

Eligibility

Key inclusion criteria

Diabetic men above 30 yrs old with hypogonadism

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

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

United Kingdom

England

Study participating centre

Medicine

Barnsley United Kingdom S75 2EP

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Barnsley Hospital NHS Foundation Trust (UK), BDGH Small Projects Fund (internal funding)

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	01/06/2006		Yes	No