

Effect of transdermal testosterone replacement in hypogonadal men with decreased insulin sensitivity

Submission date

23/01/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

06/02/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

07/04/2015

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

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Additional identifiers

Protocol serial number

TSX/01/C

Study information

Scientific Title

Effect of transdermal testosterone replacement in hypogonadal men with decreased insulin sensitivity

Acronym

TIMES2

Study objectives

To assess the effect of transdermal testosterone replacement in hypogonadal men with decreased insulin sensitivity

Ethics approval required

Old ethics approval format

Ethics approval(s)

Huntingdon Research Ethics Committee, 20/09/2005, ref: 05/Q0104/132

Primary study design

Interventional

Study design

Interventional randomised double-blind placebo-controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hypogonadal men with decreased insulin sensitivity

Interventions

Once daily testosterone replacement gel 2% versus placebo gel

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Testosterone replacement gel 2%

Primary outcome(s)

Change in insulin sensitivity

Key secondary outcome(s)

1. Change in abdominal obesity, lipid profile and glycaemic control
2. Change in symptoms of hypogonadism
3. The safety and tolerability of testosterone replacement gel compared to placebo gel

Completion date

31/08/2008

Eligibility

Key inclusion criteria

1. Hypogonadal males
2. Decreased insulin sensitivity

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

1. Use of testosterone replacement therapy in the last six months
2. History of or current prostate carcinoma

Date of first enrolment

31/01/2006

Date of final enrolment

31/08/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Royal Hallamshire Hospital

Sheffield

United Kingdom

S10 2JF

Sponsor information**Organisation**

ProStrakan Pharmaceuticals (UK)

ROR

<https://ror.org/017hh7b56>

Funder(s)

Funder type

Industry

Funder Name

ProStrakan Pharmaceuticals Ltd

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	01/04/2011		Yes	No
Results article	substudy results	21/12/2013		Yes	No