

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Interventional randomised double-blind placebo-controlled 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

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 measure

Change in insulin sensitivity

Secondary outcome measures

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

Overall study start date

31/01/2006

Completion date

31/08/2008

Eligibility

Key inclusion criteria

1. Hypogonadal males
2. Decreased insulin sensitivity

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

320

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

England

United Kingdom

Study participating centre
Royal Hallamshire Hospital
Sheffield
United Kingdom
S10 2JF

Sponsor information

Organisation

ProStrakan Pharmaceuticals (UK)

Sponsor details

Galabank Business Park
Galashiels
United Kingdom
TD1 1QH
+44 (0)189 666 4000
ewan.morrison@prostrakan.com

Sponsor type

Industry

Website

<http://www.prostrakan.com>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

ProStrakan Pharmaceuticals Ltd

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