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

Submission date	Recruitment status	[_] Prospectively registered
23/01/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/04/2015	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 Committe, 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
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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