

Testosterone therapy as an adjunct to exercise rehabilitation: effects on exercise capacity, inflammatory markers and quality of life in hypogonadal males with chronic heart failure

Submission date 21/08/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 13/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/02/2013	Condition category Circulatory System	<input type="checkbox"/> 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

Study information

Scientific Title

Acronym

TEST-EX

Study objectives

Exercise rehabilitation and adjunctive testosterone therapy will evoke greater improvements in exercise capacity, circulating inflammatory markers, cardiac and skeletal muscle function, indices of psychological health status and quality of life than exercise alone in hypogonadal males with chronic heart failure.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval granted by the South Sheffield Research Ethics Committee (REC reference number: 06/Q2308/73), date of approval: June 2nd, 2006.

Study design

Randomised double-blind placebo-controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Hypogonadal males with chronic heart failure

Interventions

Exercise alone versus exercise and adjunctive testosterone therapy.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Testosterone

Primary outcome measure

Exercise capacity at the 12 week time point in relation to baseline.

Secondary outcome measures

1. Inflammatory markers
2. Tests of cardiac and skeletal muscle function
3. Indices of psychological health status
4. Quality of life

Overall study start date

01/09/2006

Completion date

31/08/2007

Eligibility

Key inclusion criteria

1. Ambulant males
2. Over 18 years
3. Stable chronic heart failure
4. Blood testosterone level of less than 12 nmol/l
5. Symptoms of hypogonadism

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Male

Target number of participants

36

Key exclusion criteria

1. Unstable agina
2. Recent acute myocardial infarction
3. Decompensated heart failure
4. Haemodynamically significant valvular heart disease
5. Uncontrolled hypertension

6. Renal insufficiency
7. Urologic disorders
8. Orthopedic/neurologic illness limiting the ability to exercise

Date of first enrolment

01/09/2006

Date of final enrolment

31/08/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Centre for Sport and Exercise Science

Sheffield

United Kingdom

S10 2BP

Sponsor information

Organisation

Heart Research (UK)

Sponsor details

Suite 12D

Joseph's Well

Leeds

United Kingdom

LS3 1AB

Sponsor type

Charity

Website

<http://www.heartresearch.org.uk>

ROR

<https://ror.org/04j68sw28>

Funder(s)

Funder type

Not defined

Funder Name

Heart Research (UK) (reference number: RG2511/06/07)

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?
Protocol article	protocol	30/11/2006		Yes	No
Results article	results	01/12/2012		Yes	No