

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	☐ Prospectively registered ☒ Protocol
Registration date 13/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/02/2013	Condition category Circulatory System	☐ 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

RG2511/06/07

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.

Primary study design

Interventional

Study design

Randomised double-blind placebo-controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

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

United Kingdom

England

Study participating centre
Centre for Sport and Exercise Science
Sheffield
United Kingdom
S10 2BP

Sponsor information

Organisation
Heart Research (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

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