

# 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

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

**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

# 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?
<a href="#">Protocol article</a>	protocol	30/11/2006		Yes	No
<a href="#">Results article</a>	results	01/12/2012		Yes	No