

# 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

**Contact name**  
Dr John Saxton

**Contact details**  
Centre for Sport and Exercise Science  
Sheffield Hallam University  
Collegiate Crescent Campus  
Sheffield  
United Kingdom  
S10 2BP

## 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.

**Study design**

Randomised double-blind placebo-controlled trial

**Primary study design**

Interventional

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