

Thalidomide for chronic heart failure

Submission date 12/09/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/11/2013	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

N0084089156

Study information

Scientific Title

Study objectives

Is thalidomide a benefit to patients with chronic heart failure, specifically those with evidence of cachexia?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised 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

Cardiovascular: Heart failure

Interventions

Randomised controlled trial comparing a) thalidomide and b) placebo 100 mg twice daily for 12 weeks in random order. End points will be measured at baseline, crossover point and end of study.

Added 27/09/2013: this trial was stopped due to poor recruitment in 2004.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Thalidomide

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2000

Completion date

01/12/2008

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

20

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2000

Date of final enrolment

01/12/2008

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Cardiology
Cottingham, East Yorkshire
United Kingdom
HU16 5JQ

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Research organisation

Funder Name

The North and South Bank Research and Development Consortium (UK)

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