

Immune activation in chronic heart failure and the role of endotoxin

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 28/02/2020	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0201082084

Study information

Scientific Title

Immune activation in chronic heart failure and the role of endotoxin

Study objectives

To investigate whether CHF is associated with immune dysregulation and to establish whether endotoxin levels are increased in heart failure patients and whether an endotoxin challenge is a component of immune activation in patients with severe CHF. Study could lead to new therapeutic insights and could contribute to the development of new therapeutic strategies for immune activation in CHF and a syndrome currently without effective treatment ie cardiac 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)

Not Specified

Participant information sheet**Health condition(s) or problem(s) studied**

Cardiovascular: Chronic heart failure

Interventions

Study A: Randomised Controlled Trial (10 cachetic and 10 non-cachetic stable CHF patients, and 10 controls)

Study B: Cohort Observation (10 CHF patients presenting acute oedematous exacerbation)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/1997

Completion date

29/06/2006

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

01/04/1997

Date of final enrolment

29/06/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Imperial College School of Medicine NHLI

London

United Kingdom

SW3 6LY

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Royal Brompton and Harefield NHS Trust (UK) Joint Committee for Research

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?
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[Results article](#)

results

29/05/1999

28/02/2020

Yes

No