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Immune activation in chronic heart failure and the role of endotoxin

Submission date	Recruitment status	[ ] Prospectively registered
29/09/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
29/09/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/02/2020	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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
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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?

Results article	results	29/05/1999	28/02/2020	Yes	No