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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

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Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
29/06/2006

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Imperial College School of Medicine NHLI
London
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Sponsor information

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

Funder(s)

Funder type
Government

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

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