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Randomised controlled trial of Levosimendan vs Enoximone in Cardiogenic Shock

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/02/2014	Circulatory System	[ ] Record updated in last year

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
N0025128433

Study information

Scientific Title

Study objectives
Does the use of Levosimendan (a calcium sensitiser) when compared with Enoximone improve measured cardiovascular parameters whilst reducing both the incidence of dysrhythmias and the use of additional inotropic support?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective double blind 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: Cardiogenic shock

Interventions
Following assessment by the duty Consultant Intensivist invasive monitoring will be placed as part of the current standard clinical practice. All those satisfying both the inclusion and exclusion criteria will be randomised to receive either Levosimendan or Enoximone infusions, subject to obtaining their consent. The rate of loading dose and subsequent 24 hour infusion will be based on a standardised protocol. Cardiovascular parameters will be taken immediately before commencement of infusions to establish baseline readings. This data will be collected at 10 minutes, 1, 4, 6, 12 and 24 hours after starting the infusions. All members of staff will be blinded to the type of infusion given. Standard demographic and biochemical data will be collected from each patient. This will be collected on a standardised proforma by the investigators.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Levosimendan, Enoximone

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2004

Completion date
25/09/2007

Eligibility

Key inclusion criteria
1. Patients over 18 years of age.
2. All patients that are suspected of having cardiogenic shock during their admission to the Critical Care Unit will be identified.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
12 adult patients - 6 in each arm

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2004

Date of final enrolment
25/09/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Critical Care Unit
Liverpool
United Kingdom
L9 7AL

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Aintree Hospitals NHS Trust (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