

Randomised controlled trial of Levosimendan vs Enoximone in Cardiogenic Shock

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/02/2014	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
Dr Gerard Dempsey

Contact details
Critical Care Unit
Anaesthesia Department
University Hospital Aintree
Longmoor Lane
Liverpool
United Kingdom
L9 7AL
+44 (0)151 529 5152

Additional identifiers

Protocol serial number
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

Intentional

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Critical Care Unit

Liverpool

United Kingdom

L9 7AL

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Aintree Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration