ISRCTN46862968 https://doi.org/10.1186/ISRCTN46862968

A double-blind randomised controlled clinical trial of levosimendan vs dopexamine in septic shock

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 16/10/2014	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] 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
N0025154509

Study information

Scientific Title

Study objectives
To assess the role of levosimendan in preserving blood flow to the splanchnic circulation in septic shock as compared with dopexamine, with a secondary objective of whether there is improvement in cardiac performance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial (pilot study) with randomisation into two groups, double blinded

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Sepsis

Interventions
Randomised controlled trial (pilot study) with randomisation into two groups, double blinded to minimise researcher bias, patients randomised to levosimendan or dopexamine, the randomisation code to be held by a non-participating intensive care pharmacist who will track any adverse effects. Those recruited will be administered an infusion of trial or control drug based on their body weight and following a set standardised protocol. Following 24 hours infusion of the study/control drug, all patients will be converted to an infusion of dopexamine at 1 mg if use of drug is still considered necessary.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/2004

Completion date
20/09/2007

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 patients, 10 in each group, following admission to Critical Care at Aintree Trust

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/2004

Date of final enrolment
20/09/2007

Locations

Countries of recruitment
England

United Kingdom

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

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
Aintree Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding (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