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

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

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