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# Vasopressin and Corticosteroids in septic Shock

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 03/06/2010 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 10/09/2010 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 16/04/2015 | Signs and Symptoms | |

**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**
2009-017636-41

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
UKCRN ID: 8828; EudraCT: 2009-017636-41

# Study information

## Scientific Title
Vasopressin and Corticosteroids in septic Shock: an open-label randomised controlled trial

## Acronym
VACS

## Study objectives
This is an open-label randomised controlled trial. It will be conducted in the three general adult ICUs within the Imperial College Healthcare NHS Trust. All patients will be treated with vasopressin as the initial vasopressor therapy to maintain mean arterial blood pressure after adequate fluid resuscitation. If maximum doses of vasopressin are reached the patient will be treated with the randomised study drug (hydrocortisone or placebo), before additional clinically indicated vasopressors/inotropes are prescribed.

The objectives of this trial are:
1. To assess if corticosteroids increase exogenously administered vasopressin levels in septic shock
2. To assess if corticosteroids increase the blood pressure response to exogenously administered vasopressin
3. To act as feasibility study for a larger double-blind randomised controlled trial

As of 22/11/2011 the overalltrial end date has been updated. The previous date was 30/09/2011.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Oxford REC A, 18/05/2010, ref: 10/H0604/35

## Study design
Open-label randomised controlled trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Critical Care

### Interventions
Vasopressin +/- steroids; the two treatment arms will be:
1. Vasopressin (0 - 0.06 U/minute via continuous intravenous [IV] infusion) and hydrocortisone sodium phosphate (50 mg IV 6-hourly)
2. Vasopressin (0 - 0.06 U/minute via continuous IV infusion) and placebo (0.5 ml 0.9% saline IV 6 hourly)

Vasopressin will continue until shock has resolved. Hydrocortisone will continue for a maximum of 11 days. Total follow-up is 28 days.

Study entry: single randomisation only

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Vasopressin, hydrocortisone

### Primary outcome measure
Plasma vasopressin levels, measured 6 - 24 hours post-steroid administration

### Secondary outcome measures
1. Difference in vasopressin requirements between treatment groups
2. 28-day, ICU and hospital mortality rates
3. Organ failure free days in the first 28 days, assessed using the serial organ failure assessment (SOFA) score

### Overall study start date
30/08/2010

### Completion date
31/03/2012

# Eligibility

### Key inclusion criteria
The target population is adult patients who require vasopressors for the management of sepsis despite fluid resuscitation. These patients will require management on the intensive care unit.

Inclusion criteria will use the internationally-established consensus definitions of sepsis. In brief:
1. Fulfil 2/4 of the criteria of the systemic inflammatory response syndrome (SIRS) due to known or suspected infection within the previous 24 hours. The SIRS criteria are:
1.1. Fever (greater than 38°C) or hypothermia (less than 36°C)

1.2. Tachycardia (heart rate greater than 90 beats per minute)
1.3. Tachypnea (respiratory rate greater than 20 breaths per minute or partial pressure of carbon dioxide in the blood [PaCO2] less than 4.3 kPa) or need for mechanical ventilation
1.4. Abnormal leukocyte count (greater than 12,000 cells/mm3, less than 4000 cells/mm3, or greater than 10% immature [band] forms)
2. Hypotension despite adequate intravenous fluid resuscitation (minimum of 1 litre in the previous four hours)
3. Aged greater than or equal to 16 years, either sex

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
Planned sample size: 60; UK sample size: 60

### Key exclusion criteria
1. Patient has received a continuous infusion of vasopressors previously during this hospital admission (other than vasopressors used as emergency treatment to stabilise the patient during this episode). Vasopressors include noradrenaline, adrenaline, vasopressin, dopamine, metaraminol, phenylephrine.
2. Regular systemic corticosteroid therapy within the previous three months (this does not include inhaled steroid therapy)
3. End-stage renal failure
4. Known adrenal dysfunction/insufficiency
5. Physician and team are not committed to full active care
6. Patient who is terminally ill (death anticipated within 24 hours)
7. Patient is known to be pregnant
8. Patient has known acute mesenteric ischaemia
9. Patient is being actively treated for an acute coronary syndrome
10. Patient is known to have Raynaud's phenomenon, systemic sclerosis or other vasospastic diseases
11. Patient is enrolled in another interventional trial that might interact with the study drugs
12. Patients has a history of anaphylaxis to any study drug

### Date of first enrolment
30/08/2010

### Date of final enrolment
31/03/2012

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Imperial College/Charing Cross Hospital**
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# Sponsor information

**Organisation**
Imperial College London (UK)

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**Sponsor type**
University/education

**Website**
http://www3.imperial.ac.uk/clinicalresearchgovernanceoffice

**ROR**
https://ror.org/041kmwe10

# Funder(s)

**Funder type**
Government

**Funder Name**
Intensive Care Foundation (UK)

### Funder Name
National Institute for Health Research

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2014 | | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |