

Vasopressin and Corticosteroids in septic Shock

Submission date 03/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 10/09/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/04/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

2009-017636-41

Protocol serial number

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 overall trial 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

Study type(s)

Treatment

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(s)

Plasma vasopressin levels, measured 6 - 24 hours post-steroid administration

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

Imperial College/Charing Cross Hospital

London

United Kingdom

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Sponsor information**Organisation**

Imperial College London (UK)

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

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