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

Contact name

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Contact details

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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 London United Kingdom W6 8RF

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

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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