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Vasopressin and Corticosteroids in septic Shock

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anthony Gordon

Contact details
Clinical Senior Lecturer & Consultant
Critical Care Medicine
11N, Imperial College/Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF
-
anthony.gordon@imperial.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
2009-017636-41

Protocol serial number
UKCRN ID: 8828; EudraCT:

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

Primary study design
Interventional

Study design
Open-label randomised controlled trial

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
W6 8RF

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