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A randomised controlled trial of VAsopressin versus norepinephrine in Septic Shock

Submission date	Recruitment status	[_] Prospectively registered
02/11/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/08/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/10/2019	Infections and Infestations	

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
MCT-44152

Study information

Scientific Title
A randomised controlled trial of VAsopressin versus norepinephrine in Septic Shock

Acronym
VASST

Study objectives
To examine the effect of vasopressin versus norepinephrine in treatment of septic shock.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of British Columbia/Providence Health Care (UBC/PHC) Research Ethics Board, 17/11/1999

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Septic Shock

Interventions
Patient will be randomised in a blinded fashion to receive a continuous infusion of either vasopressin (experimental therapy) or norepinephrine (control therapy). The study infusion will be used as the primary means of stabilising and maintaining a patient's blood pressure.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Vasopressin, norepinephrine

Primary outcome measure
28-day survival

Secondary outcome measures
1. 90-day survival
2. Organ failure free days
3. Days alive and free of shock
4. Days alive and free of SIRS
5. Days alive and free of steroid use
6. Length of stay in the Intensive Care Units (ICU)
7. Length of stay in hospital
8. Effects on biologic markers of inflammation
9. Effect on haemodynamic variables

Overall study start date
01/06/2001

Completion date
31/01/2003

Eligibility

Key inclusion criteria
1. 776 adult patients with septic shock of either sex, 16 years and older
2. Aged greater than 16 years
3. Evidence of severe septic shock as defined by criteria listed below:
3.1. Systemic Inflammatory Response (SIRS), presence of two or more of the following:
3.1.1. Fever (temperature greater than 38°C/hypothermia less than 36°C)
3.1.2. Tachycardia (heart rate greater than 90 beats per minute)
3.1.3. Tachypnea (respiratory rate greater than 20 breaths per minute or PaCO2 32 torr or mechanically ventilated)
3.1.4. Pathologic white blood cell count (greater than 12,000 cells/mm^3, less than 4000 cells /mm^3, or greater than 10% immature band forms)
3.2. Known (culture positive) or suspected (cultures pending, patient on antibiotics) source of infection (defines sepsis)
3.3. Evidence of one new organ dysfunction (defines severe sepsis):
3.3.1. Lung (ventilated and partial pressure of oxygen in arterial blood [PaO2]/fraction of inspired oxygen [FiO2]) less than 300
3.3.2. Renal (urine output less than 30 ml/hour or less than 0.5 ml/kg body weight, for at least 1 hour)
3.3.3. Coagulation (platelet count less than 80,000/mm^3)
3.3.4. Central nervous system (CNS) (Glasgow coma scale less than 12)
3.4. Hypotension and need for vasopressors (defines severe septic shock):
3.4.1. Systolic blood pressure (SBP) less than 90 mmHg or decrease in SBP by at least 40 mmHg for more then one hour while central venous pressures remain adequate (greater than or equal to 12 mmHg) or at least 500 ml of saline was infused. Duration of hypotension may be less than one hour if vasopressors are infused to maintain blood pressure, and requirement for vasopressor support (norepinephrine equivalent) = (dopamine ÷ 2 µg/kg/min) + norepinephrine (µg/min) + epinephrine (µg/min) + phenylephrine ÷ 20 (µg/min) greater than or equal to 5 µg/min

for at least six consecutive hours in the last 24 hours and on at least 5 µg/min within the last hour prior to randomisation, or severe septic shock: vasopressor support (norepinephrine equivalent, as above) greater than or equal to 15 µg/min in the last hour prior to randomisation
4. Central venous catheter (pulmonary-arterial catheter is optional)

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
776

Key exclusion criteria
1. Physician and team are not committed to aggressive care
2. Patient who is terminal (death anticipated in 12 months)
3. Greater than 24 hours have elapsed since the patient met entry criteria
4. Patient is pregnant (pregnancy test required in all women less than 50 years)
5. Underlying chronic heart disease (New York Heart Association [NYHA] class III or IV) and shock
6. Unstable angina or myocardial infarction manifest by chest pain and S-T segment elevation within the previous 30 days
7. Acute mesenteric ischemia present or suspected
8. Severe hyponatremia (Na less than 130 mmol/l)
9. Patient has raynaud's phenomenon, systemic sclerosis or vasopastic diathesis
10. Traumatic brain injury (Glasgow Coma Score [GCS] less than 8 prior to onset of sepsis)

Date of first enrolment
01/06/2001

Date of final enrolment
31/01/2003

Locations

Countries of recruitment
Canada

Study participating centre
St Paul's Hospital
Vancouver
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Sponsor information

Organisation
University of British Columbia (Canada)

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Sponsor type
University/education

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-44152)

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	28/02/2008		Yes	No
Results article	results	01/01/2010		Yes	No
Results article	results	01/01/2010		Yes	No
Other publications	resutls	11/08/2011		Yes	No
Results article	results	01/09/2012		Yes	No
Results article	results	20/06/2013		Yes	No
Results article	results	01/08/2013		Yes	No
Results article	results	01/10/2018	01/10/2019	Yes	No