

A randomised controlled trial of VAsopressin versus norepinephrine in Septic Shock

Submission date 02/11/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/08/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/10/2019	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr James Andrew Russell

Contact details
St Paul's Hospital
Rm 240 Comox Building
1081 Burrard Street
Vancouver
Canada
V6Z 1Y6
+1 604 806 2872
jrussell@mrl.ubc.ca

Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

28-day survival

Key secondary outcome(s)

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

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/mm³, less than 4000 cells/mm³, 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/mm³)
 - 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 than 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

16 Years

Sex

All

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

Canada

V6Z 1Y6

Sponsor information**Organisation**

University of British Columbia (Canada)

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

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
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
Other publications	results	11/08/2011		Yes	No