

# The Vasopressin in Pediatric Vasodilatory Shock Trial

<b>Submission date</b> 10/06/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/01/2012	<b>Condition category</b> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
KC1; MCT-80549

# Study information

## Scientific Title

Vasopressin in pediatric vasodilatory shock: a multicentre, two armed, placebo controlled randomised parallel trial

## Acronym

VIP Trial

## Study objectives

Current hypothesis as of 20/12/2007:

In pediatric patients with vasodilatory shock who are refractory to standard vasoactive agents, low dose arginine vasopressin (AVP) will maintain adequate blood pressure and perfusion, thus reducing standard vasoactive infusion requirements.

Previous hypothesis:

"Warm shock" is a condition that occurs due to a variety of causes, and results in a significant number of deaths in both adults and children. The primary mechanism of death in warm shock is low blood pressure, which leads to inadequate blood and oxygen supply to vital organs. Multiple drugs have been used to control blood pressure and reverse shock, however patients often remain resistant to these medications. Hence side effects of these drugs are often seen, before their proposed effect occurs. Vasopressin, a drug which has been used for over 50 years for other conditions, has recently been shown to improve blood pressure in shock, where other drugs have failed. It appears to act directly to reverse the underlying mechanisms of shock, and has additional advantages over traditionally used medications. We are conducting a study to examine if vasopressin is effective and safe to use in critically ill children who suffer from warm shock.

Please note that as of 20/12/2007 this trial record was extensively updated with information from the funder, the Canadian Institutes of Health Research (CIHR). All updates are recorded under the date 20/12/2007. The anticipated start and end dates of this trial have also been updated; the previous anticipated start and end dates of this trial were:

Anticipated start date: 01/10/2006

Anticipated end date: 30/09/2007

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Added as of 20/12/2007:

Ethics approval received from the Research Ethics Board of Hamilton Health Sciences (Ontario) on the 21st May 2003 (ref: 03-157).

## Study design

Added as of 20/12/2007:

Multicentre randomised double blind two armed placebo controlled parallel group trial with study participant, study investigator, caregiver, and data analyst blinded.

## 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**

Pediatric vasodilatory shock

**Interventions**

Current interventions as of 20/12/2007:

1. Pressyn® AR, dose: 0.0005 units/kg/min, duration: until the patient is weaned off all open-labelled vasoactive agents
2. Placebo (normal saline), administered at the same volume, rate (maximum mls/hour) and duration as the active study drug

Previous interventions:

Patients will be randomized to receive an intravenous (IV) infusion of either low dose Arginine Vasopressin (AVP) (0.0005 u/kg/min to 0.002 u/kg/min) or placebo, in addition to the open labeled catecholamine pressors which they are already receiving. The study drug infusion will be titrated to a target mean arterial blood pressure appropriate for age.

Contact for public queries:

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website: <http://www.chalmersresearch.com>

The previous sponsor for this trial was Hamilton Health Sciences (Canada). This has been updated on 20/12/2007.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Vasopressin

### **Primary outcome measure**

Added as of 20/12/2007:

Time to vasoactive-free hemodynamic stability measured as time in hours from study drug administration to time when all vasopressor/inotropic agents are successfully discontinued.

### **Secondary outcome measures**

Added as of 20/12/2007:

1. Multiple organ dysfunction syndrome (MODS), measured by Delta PELOD - difference between MODS at study entry and worst value recorded during pediatric intensive care unit (PICU) stay
2. Organ Failure Free Days, measured up to 30 days post study drug administration
3. Mortality measured up to 30 days post study drug administration

### **Overall study start date**

01/09/2003

### **Completion date**

30/06/2007

## **Eligibility**

### **Key inclusion criteria**

Current inclusion criteria as of 20/12/2007:

1. Age: 1 month to 18 years, either sex
2. Vasodilatory shock: patient must be within 24 hours of fulfilling criteria 2.1. and 2.2.:
  - 2.1. Fluid and catecholamine refractory shock: patient must fulfill criteria 2.1.1. and 2.1.2.:
    - 2.1.1. Fluid administration (greater than or equal to 40 ml/kg crystalloid/colloid)
    - 2.1.2. Minimum vasoactive infusion requirement for eligibility - either one of:
      - 2.1.2.1. Dopamine greater than or equal to 10 µg/kg/min
      - 2.1.2.2. Any dose of epinephrine, norepinephrine or phenylephrine
  - 2.2. Clinical evidence of Vasodilation/Warm shock. These physical signs may be present at any time, including prior the institution of the vasoactive infusions listed in point 2.1.2.: patient must fulfill criteria 2.2.1., plus any two of the three criteria 2.2.2., 2.2.3. or 2.2.4. for eligibility:
    - 2.2.1. Low diastolic blood pressure (BP) (as defined by diastolic BP less than half systolic BP value)
    - 2.2.2. Tachycardia (as defined by heart rate [HR] greater than 2 SD for age)
    - 2.2.3. Warm extremities
    - 2.2.4. Flash capillary refill
3. Arterial line
4. Central venous line (a pulmonary artery catheter is optional)
5. Commitment of intensive care unit (ICU) team to full aggressive support
6. Informed consent: from parent or appropriate substitute decision-maker

Previous inclusion criteria:

1. Pediatric patients with vasodilatory shock, despite volume resuscitation and catecholamine pressor administration
2. Children greater than 1 month and less than 18 years of age, either sex

### **Participant type(s)**

Patient

**Age group**

Child

**Lower age limit**

1 Months

**Upper age limit**

18 Years

**Sex**

Both

**Target number of participants**

69 (added as of 20/12/2007)

**Key exclusion criteria**

Added as of 20/12/2007:

1. Terminal illness (death anticipated in 24 hours, or withholding therapy considered)
2. Pregnancy
3. Known history of hypersensitivity to exogenous vasopressin
4. Cardiac Index less than or equal to 2.5 L/min/m<sup>2</sup> after fluid resuscitation (this is in the event that a formal cardiac index measurement has been performed, e.g. by Echo or Swan Ganz catheter)
5. Severe hyponatremia (serum sodium less than 125 mM) not responding to water restriction
6. Known history of vasospastic diathesis, e.g. Raynaud's phenomenon
7. Concurrent use of intravenous vasodilator agents: i.e. sodium nitroprusside, within 12 hours of phenoxybenzamine use
8. Patient who has received intravenous vasopressin or vasopressin analogue within 24 hours of eligibility
9. Diagnosis of syndrome of inappropriate antidiuretic hormone secretion (SIADH) or Diabetes Insipidus
10. Inability to obtain informed consent
11. Previous enrollment in the VIP study

**Date of first enrolment**

01/09/2003

**Date of final enrolment**

30/06/2007

**Locations**

**Countries of recruitment**

Canada

**Study participating centre**

**Hamilton Health Sciences**

Hamilton  
Canada  
L8N 3Z5

## Sponsor information

**Organisation**

Childrens Hospital of Eastern Ontario Research Institute (CHEORI) (Canada)

**Sponsor details**

c/o Ms. Laura Goyer  
Assistant Grants Administrator  
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Ottawa, Ontario  
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+1 613 737 7600 ext. 4165  
lgoyer@cheo.on.ca

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.cheori.org/>

**ROR**

<https://ror.org/05nsbhw27>

## Funder(s)

**Funder type**

Research organisation

**Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-80549)

**Funder Name**

Toronto Hospital for Sick Children Foundation (Canada)

**Funder Name**

Physician's Services Incorporated (PSI) Foundation (Canada)

**Funder Name**

Ferring Pharmaceuticals (Canada)

**Funder Name**

Added as of 20/12/2007:

**Funder Name**

Laerdal Inc. (Canada)

**Funder Name**

Queen's University Research Fund (Canada)

**Funder Name**

Canadian Intensive Care Foundation (Canada)

**Funder Name**

Heart and Stroke Foundation of Ontario (Canada)

## 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?
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<a href="#">Results article</a>	results	01/10/2009	Yes	No
<a href="#">Results article</a>	results	01/11/2011	Yes	No