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The Vasopressin in Pediatric Vasodilatory Shock Trial

Submission date 10/06/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/09/2003	**Overall study status** Completed	
Last Edited 26/01/2012	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Karen Choong

Contact details
Hamilton Health Sciences
1200 Main St. W.
Room 3G49
Hamilton
Canada
L8N 3Z5
+1 905 521 2100 ext. 76610
choongk@mcmaster.ca

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:
Barbara Murchison RN, CCRP
Research Coordinator, Chalmers Research Group
CHEO Research Institute
401 Smyth Road, Room 212B
Ottawa, Ontario
Canada K1H 8L1
Tel: +1 613 737 7600 ext. 4133
Fax: +1 613 738 4800
Email: bmurchison@cheo.on.ca
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 measaured 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^2 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
401 Smyth Road
Ottawa, Ontario
Canada
K1H 8L1
+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?

Results article	results	01/10/2009	Yes	No
Results article	results	01/11/2011	Yes	No