

## Secure login portal

### Research study title, logo, and contact information



# CHEO

## The SHIPSS Trial

### Sign in

Username:

Password:

**Log In**

[Forgot your password?](#)

[Change your password](#)

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### Contact

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Site Administrator: [dms@ohri.ca](mailto:dms@ohri.ca)

# Participant list with search feature







# SHIPSS

STRESS HYDROCORTISONE IN PEDIATRIC SEPTIC SHOCK

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## Participant List

*(To randomize a new participant, click on the red plus button above. To view a participant record, click on the green arrow icon.)*

	Random Number	Random Date & Time	Screening No	SiteNo	CreatedUser
	999-0001	31-Jan-2019 15:38	999S002	999	TestRC
	999-0002	04-Feb-2019 08:17	999S001	999	TestRC
	999-0003	12-Feb-2019 10:51	999S003	999	TestRC
	999-0004	14-Feb-2019 12:02	999S009	999	TestRC

# Study Dashboard



# SHIPSS

STRESS HYDROCORTISONE IN PEDIATRIC SEPTIC SHOCK

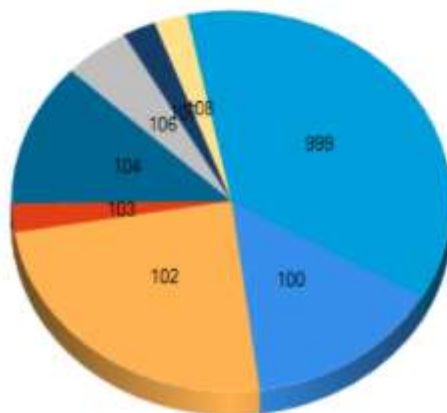
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## SHIPSS Trial Dashboard

Stress Hydrocortisone in Pediatric Septic Shock (The SHIPSS trial).

[Contact](#)[Site List](#)[Enrollment](#)

Site	Site #	Total Enrolled
Children's Hospital of Eastern Ontario	100	6
London Health Sciences Centre	102	10
McMaster Children's Hospital	103	1
Ste Justine Children's Hospital	104	5
Centre hospitalier de l'Université Laval	106	2
Saskatoon Children's Hospital	107	1
Alberta Children's Hospital	108	1
TEST Site	999	15



# An eligibility criteria checklist (IWRS)



**SHIPSS**  
STRESS HYDROCORTISONE IN PEDIATRIC SEPTIC SHOCK

**Log Out**

User ID: TestRC  
Site ID: 999

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## SHIPSS TRIAL ELIGIBILITY CRITERIA

Screening No.:  (###S###) Screening Date:

**Inclusion Criteria: To be randomized, participant must meet all of the inclusion criteria (Yes)**

*Note: In order to be screened, the participant must be receiving vasoactive-inotropic*

### support

- |    |   |                           |                          |
|----|---|---------------------------|--------------------------|
| I1 | Age is at least 1 month (with corrected gestational age $\geq 42$ weeks), but less than 17 years and 8 months at the time of screening;   | <input type="radio"/> Yes | <input type="radio"/> No |
| I2 | A focus of infection has been documented or there is a strong suspicion of infection upon admission to PICU or for patients who develop septic shock during PICU stay, at the onset of the septic shock event;  | <input type="radio"/> Yes | <input type="radio"/> No |
| I3 | Surveillance cultures (e.g. blood, urine, cerebral spinal fluid, wound) and/or other microbial diagnostic tests have been obtained;   | <input type="radio"/> Yes | <input type="radio"/> No |
| I4 | One or more antimicrobials have been prescribed;  | <input type="radio"/> Yes | <input type="radio"/> No |
| I5 | Core temperature $>38.5$ C or $<36.0$ C or a change of $\geq 1.5$ C from baseline core temperature or leukocytosis or leukopenia OR a left-shifted leukocyte differential with $>10\%$ immature granulocyte forms OR a neutrophil count of $<0.5 \times 10^9$ cells per litre has been documented at least once within the last 24 hours; | <input type="radio"/> Yes | <input type="radio"/> No |
| I6 | Treatment with a continuous infusion of vasoactive-inotropic agent(s) to maintain mean or systolic arterial blood pressure above the age-appropriate target set by the treating clinician;  | <input type="radio"/> Yes | <input type="radio"/> No |
| I7 | Administration of two or more vasoactive-inotropic agents OR epinephrine or norepinephrine infusion alone at greater than or equal to $\geq 0.10$ mcg/kg/min for $>1$ hour;   | <input type="radio"/> Yes | <input type="radio"/> No |

Date and time that the participant met all inclusion criteria (start of 12-hour window for enrolment and administration of first dose of study drug);

Date:  \*(dd-mmm-yyyy) Time:  \*(HH:mm,00:00 - 23:59, 24-hour)

**Exclusion Criteria: To be randomized, participant must not meet any of the exclusion criteria (No)**

- |    |   |                           |                          |
|----|---|---------------------------|--------------------------|
| E1 | All inclusion criteria have been present for $> 12$ hours;  | <input type="radio"/> Yes | <input type="radio"/> No |
| E2 | Attending physician expects to prescribe systemic corticosteroids for an indication other than septic shock;  | <input type="radio"/> Yes | <input type="radio"/> No |
| E3 | Participant has received any doses of systemic corticosteroids during treatment for sepsis;   | <input type="radio"/> Yes | <input type="radio"/> No |
| E4 | Enrolled concurrently in a competing interventional clinical trial (formal assessment to be conducted by SHIPSS Core Committee for each potential competing trial); | <input type="radio"/> Yes | <input type="radio"/> No |

# Participant form list with form status and query



**SHIPSS**  
STRESS HYDROCORTISONE IN PEDIATRIC SEPTIC SHOCK

**Log Out**

User ID: TestRC  
Site ID: 999

me	Screening List	Randomization List	Resource Documents	Extract Data
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	<b>Participant Number:</b> 999-0001	<b>Randomization Date:</b> 31-Jan-2019	<b>Site:</b> 999
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Participant Forms	Status/Query
0. Randomization Results	
1. Demographics & Consent	
2. Medical History	
3. Infection Data	
4. Daily Data and Organ Dysfunction in PICU	
5. Daily Data and Organ Dysfunction in Hospital Ward	
6. Length of Interventions for Organ Dysfunction	
7. Study Drug and Open-Label Steroid Use	
8. PICU and Hospital Discharge	
9. Adverse Event Documentation	
10. Protocol Deviation Documentation	
11. 28-Day Follow-Up	
12. 90-Day Follow-Up	
13. PERSEVERE and Endotype Analysis	
14. Co-Enrolment	
<b>Scores</b>	
Risk of Mortality at PICU Admission (PRISM IV)	
PELOD-2	
POPC	

# Participant demographic form



Participant Number: 999-0001

Randomization Date: 31-Jan-2019

Site: 999

## Form 1: Demographics and Consent Info



1 Date of birth:  \*(dd-mmm-yyyy) Age:  (months) Gender:  Male  Female  
*If your site does not allow you to collect date of birth, enter the patients age in months at the time of enrollment instead. If your site allows you to collect date of birth, you do not need to enter age in months.*

2 PRISM IV Score:

### Consent: (Deferred Consent)

#### IF DEFERRED CONSENT WAS USED:

1 Reason deferred consent was used (Check all that apply):

- Parent(s)/guardian(s) not at beside
- Parent(s)/guardian(s) had not been updated on child's medical condition
- Care team did not want family approached at this time
- Insufficient time remaining in enrolment window
- Language barrier – translator required
- Patient in protective custody
- Other, specify

2 Was consent for continued participation obtained following enrolment via deferred consent:

3a Date & Time informed consent was obtained following enrolment via deferred consent:  \*(dd-mmm-yyyy)  (HH:mm 24-hour)

#### DOCUMENTATION OF INFORMED CONSENT

Check Yes or No for each of the following questions to document the informed consent process for either a priori informed consent or for informed consent obtained following enrollment via deferred consent. If the answer to any question is "No", please explain in the comment box below.

# Medical History form



Participant Number: 999-0001

Randomization Date: 31-Jan-2019

Site

## Form 2: Medical History and Clinical Info

1 Past medical history: (Check all that apply):

- Prematurity (< 37 weeks post-menstrual age)
- Asthma (prescribed bronchodilators or steroids)
- Other chronic steroid (glucocorticoid) therapy
- Bronchopulmonary dysplasia (BPD)
- Cystic fibrosis
- Metabolic disorder
- Diabetes

2 Immunodeficiency:  Yes  No

If immunodeficiency present, provide detail regarding cause: (Check all that apply):

- Congenital immunodeficiency
- Hematopoietic stem cell transplantation
- Human immunodeficiency virus infection
- Malignancy with chemo-radiotherapy...

3 Any known genetic syndrome?  Yes  No If Yes, name of syndrome:

### Residence/Disposition:

1 Residence/disposition: (Check all that apply): (Primary residence of child over the past 12 months; if child is <1 year, primary residence since birth)

- Home with parents/guardian
- Home with outpatient rehabilitation program
- Home with skilled nursing
- Foster care
- Chronic care or rehabilitation facility

### Admission:

1 Date of hospital admission:  \*(dd-mmm-yyyy)

2 Date of arrival to PICU:  \*(dd-mmm-yyyy)

3 Time of arrival to PICU:  \*(HH-mm 24-hour)

## Data Extraction form

(Extract all study data to MS Excel 24/7/365)



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### Data Extraction

Select tables to extract

[Select All](#)[Clear](#)

- Screening
- Q0 - Participant
- Q1 - Demographics & Consent
- Q2 - Medical History
- Q3 - Infection Data
- Q4 - Daily Data and Organ Dysfunction in PICU
- Q5 - Daily Data and Organ Dysfunction in Hospital Ward
- Q6 - Length of Interventions for Organ Dysfunction
- Q7 - Study Drug and Open-Label Steroid Use
- Q8 - PICU and Hospital Discharge
- Q9 - Adverse Event Documentation
- Q10 - Protocol Deviation Documentation
- Q11 - 28-Day Follow-Up
- Q12 - 90-Day Follow-Up
- Q13 - PERSEVERE and Endotype Analysis
- Q14 - Co-Enrolment
  
- Risk of Mortality at PICU Admission (PRISM IV)
- PELOD-2
- POPC
- Functional Status Scale (FSS)
- Family Impact Module
- PEDSQL

**Filters** (Leave blank for all records)

End Date:

[Exit](#)[Generate](#)