

**PRoMPT BOLUS Study**  
This patient has been randomized to:

**Balanced Fluids**  
Lactated Ringers or Plasmalyte  
per clinician preference  
for bolus and maintenance fluids

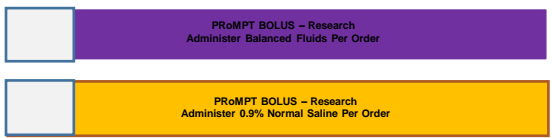
Randomization Number: **IWK-###**

**PRoMPT BOLUS Study**  
This patient has been randomized to:

**0.9 % Normal Saline**  
for bolus and maintenance fluids

Randomization Number: **IWK-###**

### Randomization Labels



### Participant Wrist Bands

**PRoMPT BOLUS**  
PRoMPT Pediatric Trial of Balanced vs Normal Saline Fluid in Sepsis

**RESEARCH**

Administer:

**Balanced Fluids**  
(Lactated Ringers or Plasmalyte A)

for all fluid administration (bolus and maintenance) until 11:59pm the day following ED randomization

Fluid Start Date & Time

\_\_\_\_\_ at \_\_\_\_\_

**PRoMPT BOLUS**  
PRoMPT Pediatric Trial of Balanced vs Normal Saline Fluid in Sepsis

**RESEARCH**

Administer:

**0.9% Normal Saline**  
(0.9% NaCl)

for all fluid administration (bolus and maintenance) until 11:59pm the day following ED randomization

Fluid Start Date & Time

\_\_\_\_\_ at \_\_\_\_\_

### IV Pole Hang Tags

**PRoMPT BOLUS**  
PRoMPT Pediatric Trial of Balanced vs Normal Saline Fluid in Sepsis

**RESEARCH PARTICIPANT**

This child has been randomized in the Emergency Department (ED) to receive:

**Balanced Fluids** (Lactated Ringers or Plasmalyte A)

for all fluid administration (bolus and maintenance) until 11:59pm the day following ED randomization

Fluid Start Date & Time

\_\_\_\_\_ at \_\_\_\_\_

For questions call Dr. Jason Emley at 902-478-8050 or email Jason.Emley@edsh.ath.ia

**PRoMPT BOLUS**  
PRoMPT Pediatric Trial of Balanced vs Normal Saline Fluid in Sepsis

**RESEARCH PARTICIPANT**

This child has been randomized in the Emergency Department (ED) to receive:

**Normal Saline (0.9% NaCl)**

for all fluid administration (bolus and maintenance) until 11:59pm the day following ED randomization

Fluid Start Date & Time

\_\_\_\_\_ at \_\_\_\_\_

For questions call Dr. Jason Emley at 902-478-8050 or email Jason.Emley@edsh.ath.ia

### Patient Door Signs

## The Randomization Envelope



### ED Study Instructions + FAQ

**ED Team Instructions**  
IWK Children's Health Centre

**PRoMPT BOLUS**  
PRoMPT Pediatric Trial of Balanced vs Normal Saline Fluid in Sepsis

- Complete study Eligibility Form in full:
  - Sign and Date form as soon as randomization occurs
  - After randomization a patient label to eligibility form (note: if it is subsequently deemed to NOT be eligible, please put form in back pouch of envelope attached to box and, if possible, please send a text email to [prprompt@edsh.ath.ia](mailto:prprompt@edsh.ath.ia) or leaving the team know)
- Identify Fluid Allocation:
  - Fluid outlined in this package is the fluid to be administered (colour coded)
    - 0.9% Normal Saline (0.9% NaCl)
    - Balanced Fluids (LR - ppr18) - Lactated Ringers OR Plasmalyte (clinician preference)
- For ALL bolus and maintenance fluid provided in this ED:
  - Order the fluid type (NS or BF) specified by the randomization information
  - NOTE: Hypotonic fluids (i.e. D45W) are NOT considered appropriate for bolus or maintenance fluids in septic children and should be avoided
  - When and how much fluid should be decided based on clinical need by the clinical care team
  - Obtain fluids from clinical ED inventory
- Write date and time of fluid start on IV hang tag and door signs where indicated:
  - Hang IV hang tag on IV pole
- Place the patient bracelet on the patient wrist
- Provide Caregiver with the Caregiver Information Sheet:
  - This study is approved to be conducted under a deferred consent model
  - The patient/caregiver will not consent before randomization/fluid administration occurs
  - A member of the study team will approach the family when it is clinically appropriate
- Communicate with admitting team:
  - Verbally inform the admitting team that the child is participating in the PRoMPT BOLUS Study and which fluids they have been allocated to
  - Provide the admitting team with (patient) location sheet
  - Impatient teams should continue to order study fluid TYPE (NS or BF) through 23:59 on the calendar day following randomization.
- If patient is discharged from ED – discontinue fluids at discharge and place forms in the medical chart:
  - Email [prprompt@edsh.ath.ia](mailto:prprompt@edsh.ath.ia) from an IWK or NS Health email the patient's number and randomization ID number
- Place forms (Eligibility Form, Door Sign, Impatient Instructions) with the patient chart BEFORE transfer or admission
  - After second randomization closer to medical chart (in nursing notes section)

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### Inpatient Study Instructions + FAQ

**Inpatient/PICU Team Instructions**  
IWK Children's Health Centre

**PRoMPT BOLUS**  
PRoMPT Pediatric Trial of Balanced vs Normal Saline Fluid in Sepsis

- Receive patient, and their email (from an IWK or NSHealth email) study team at:
  - [prprompt@edsh.ath.ia](mailto:prprompt@edsh.ath.ia) with
    - Randomization ID number (see medical chart)
    - Patient's number
    - Location of patient
- Identify Fluid Allocation:
  - Documents and treatment assignment are colour coded
    - Normal Saline
    - Balanced Fluids (Lactated Ringers or Plasmalyte)
- The Caregiver has received a Caregiver Study Information Sheet:
  - This study is approved to be conducted under a deferred consent model
  - The patient/caregiver will not consent before randomization/fluid administration occurs
  - A member of the study team will approach the family when it is clinically appropriate
  - This will be a member of the ED Research Team for all admitting locations
- Order fluids through standard IWK approved order sheets as one would for any patient for ALL bolus and maintenance fluid provided through 23:59 on the calendar day following randomization:
  - Place order the fluid TYPE specified by randomization (normal saline or balanced fluids)
  - NOTE: Hypotonic fluids (i.e. D45W) are NOT considered appropriate for bolus or maintenance fluids in septic children and should be avoided
  - When and how much fluid should be decided based on clinical need by the clinical care team
  - Obtain fluids from clinical inventory
  - Discontinue ALL IV or ED fluid given to the patient during this time
- Keep any study forms that have moved with the patient with the medical chart:
  - Hang door sign with fluid start and stop date from ED on door of patient room
- Questions - Contact Information:
  - Dr. Jason Emley (Site PI) at (902) 293-5857 or email [jason.emley@edsh.ath.ia](mailto:jason.emley@edsh.ath.ia)
  - Nick McCaughey (Study Coordinator) at (902) 470-8822 or email [nicmccaughey@edsh.ath.ia](mailto:nicmccaughey@edsh.ath.ia)
- More information available on PULSC – see PRoMPT BOLUS

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### Caregiver Information

**PRoMPT BOLUS**  
PRoMPT Pediatric Trial of Balanced vs Normal Saline Fluid in Sepsis

**INFORMATION SHEET FOR PARENTS AND/OR LEGAL GUARDIANS**

Study Title: Pragmatic Pediatric Trial of Balanced Versus Normal Saline Fluids in Sepsis (PRoMPT BOLUS)

Project Site Investigator: Dr. Jason Emley Telephone: 902-478-8050

Research Coordinator: Nick McCaughey Telephone: 902-478-8822

You child has been enrolled into a research study. This process was approved by the IWK REB because the study is safe and practically beneficial to participants, and because it compares two treatments that we know both work and are commonly used to treat your child's condition. Your child's doctor determined that giving fluids through an intravenous (IV) was needed to treat your child. Because IV fluids needed to be kept open, there was not time to review all details of the study and obtain your consent prior to beginning treatment.

There were two oral (I) fluid options: Normal Saline and Balanced Fluids (either Lactated Ringer's (LR) or Plasmalyte (PL)). All of these fluids are approved to treat open lines. We do not know if either Normal Saline or Balanced Fluids is best.

Doctors at IWK Health are doing this study to see if Normal Saline or Balanced Fluids is better in the treatment of sepsis. As part of the research your child will receive either Normal Saline or Balanced Fluids, your doctors are still in charge of when and how much fluid to give (and all other aspects of your child's care).

We know that it is very important for you to understand what the PRoMPT BOLUS study is. A member of the research team will arrange for a time to meet with you to provide more detailed information about the study and to respond to any and all of your questions.

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