

Frequently Asked Questions (FAQs)



PRoMPT BOLUS

PRagMatic Pediatric Trial of Balanced vs nOrmal Saline FLUid in Sepsis

Inpatient/PICU – London Health Sciences Centre (LHSC)

Q: What is this study all about?

A: The PRoMPT BOLUS study will determine if resuscitation with balanced fluids results in improved outcomes in children aged 2 months to <18 years presenting to the Emergency Department with sepsis.

Q: Will children who become septic on the ward/in the PICU be eligible for enrollment?

A: No. This study is enrolling exclusively in the Emergency Department. This is to avoid any confounding from fluids previously administered on the ward, in the PICU or during transport.

Q: How will I know if my patient is enrolled in the study?

A: The ED clinical staff will inform the admitting team about enrollment during handover.

We are using multiple colour-coded visual cues (**Green = Balanced Fluid**, **Yellow = Normal Saline**) to let you know about the study:

- 1) Patient Wrist Band
- 2) IV Hang Tag

Q: Will I know which fluids my patient is allocated to?

A: Yes. This is an open-label study (i.e. not blinded).

Multiple colour-coded visual cues (**Green = Balanced Fluid**, **Yellow = Normal Saline**) will remind you what fluid the participant has been allocated to.

Q: How much IV fluid should I order?

A: The amount, timing and rate of fluid administered is at the discretion of the managing health care provider.

Q: Are there special study-specific fluid bags?

A: No. You will use the fluids that are available as part of the routine hospital stock.

Q: Can I use a different fluid than the one my patient is allocated to?

A: Adherence to the allocated fluid is very important to maintain the quality of the evidence derived from the study. However, if there is a *definitive clinical indication* for using an alternate fluid from the one allocated for the study, please manage the patient based on that clinical requirement (note: these cases should be rare/exceptional). An example would be using saline for clinically relevant hyponatremia.

Q: Can I add electrolytes, dextrose, etc?

A: Yes. Some patients will require added electrolytes, dextrose etc.

Q: What about mixing medication infusions?

A: Please follow routine pharmacy directives for mixing medications, regardless of what study fluid your patient has been allocated to.

Q: Are there any compatibility issues?

A: There are several well-known compatibility issues for Lactated Ringers (LR). LR cannot be provided through the same IV line at the same time as ceftriaxone or some blood products. Options include the use of a second IV line, or a very careful IV flush prior to- and after- the use of these medications. Please review and follow all pharmacy administration guidelines for all medication administration and compatibility concerns.

Q: When does the study intervention end?

A: The study intervention period continues until midnight the day following randomization. The allocated fluid should be provided until that point. Following the intervention period, you can continue the allocated fluid should you choose, or switch to any fluid of your choice.

Note: the date/time of randomization will be written on the IV Hang Tags

Q: What about other interventions like antibiotics, vasoactive medications etc.?

A: This study only controls the type of fluid administered to the child. ALL other interventions are to be done according to best practice at the discretion of the managing health care provider.

Q: Are there any reasons I should withdraw a child from the study?

A: There are several rare but concerning clinical situations in which a child should be stopped from the study. These include:

- 1) Significant electrolyte abnormalities such as hyperkalemia and hypercalcemia, **confirmed on repeat testing**
- 2) Significant end organ damage such as severe hepatic or renal impairment,
- 3) Hypersensitivity to the allocated fluid

Formal definitions of Stopping Criteria can be found on the PRoMPT BOLUS website.
See QR code for link.

Q: What should I do if a child meets Stopping Criteria?

A: If a child meets one of the Stopping Criteria, they are no longer required to receive the allocated study fluid. Manage the child at your discretion. However, the child is still a study participant and we need to collect safety data outcomes. Please notify the study team that the child had been enrolled but met stopping criteria.

Q: What about consent?

A: Due to the emergent nature of sepsis, and the need for immediate administration of fluid management, it is not feasible to obtain true informed consent at the time of fluid initiation in the ED. This study has been approved by our local REB for deferred consent.
A Caregiver Information Sheet was provided to the family in the ED. A member of the research team will approach the family at the most optimal time to further discuss the study and obtain deferred consent.

Q: HELP!!! I have questions about the patient in front of me...what do I do?

A: Please refer to the following resources for more help:

- 1) ED Study Information Sheet
- 2) PRoMPT BOLUS website (see QR code for link)
- 3) Contact a study team member
 - **Dr. Gary Joubert** at (519) 851-7989 or Gary.Joubert@lhsc.on.ca
 - **Dr. Gurinder Sangha** at #15556 or Gurinder.Sanghi@lhsc.on.ca
 - Study team pager (Mon-Fri, 08:00-16:00): #17561 / Patrick.Siedlecki@lhsc.on.ca

