PRoMPT BOLUS

PRagMatic Pediatric Trial of Balanced vs nOrmaL Saline FlUid in Sepsis

PRoMPT BOLUS STUDY SUMMARY

WHO
Children aged 2 months to <18 years presenting to the Emergency Department (ED) with suspected sepsis who require >20cc/kg for concerns of poor perfusion.

WHAT
Pragmatic, open-label randomized clinical trial comparing the efficacy and safety of Balanced Fluids[1] vs 0.9% Saline. The primary outcome is MAKE30, a composite endpoint of new renal replacement therapy, persistent kidney dysfunction and death.

WHEN
Recruitment will take place over 4½ years, starting across Canada 2022. The target sample size is 8800, with approximately 2700 enrolled in Canada.

WHERE
13 sites across Canada, in collaboration with hospitals in the United States (PECARN), Australia and New Zealand (PREDICT).

WHY
Traditionally 0.9% Saline has been used for fluid resuscitation in children with sepsis. However, large volume resuscitation with 0.9% Saline have been shown to cause hyperchloremic metabolic acidosis, increased vascular permeability, renal perfusion changes, coagulopathy and inflammation, all leading to fluid overload, acute kidney injury, increased length of stay and mortality. Recent evidence points to decreased risk of kidney injury and death with the use of balanced fluid resuscitation.

HOW
Eligible children will be enrolled in the ED using Deferred Consent[2]
Participating children will receive the allocated fluid for boluses and maintenance until midnight the day following enrolment. All remaining management, including volumes and rates of fluid administration, are at the discretion of the responsible clinical team.

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[1]Balanced Fluids include Lactated Ringers and Plasmalyte. Either can be used at the discretion of the managing health care provider.
[2]Deferred Consent – due to the emergent need to provide fluid to children with sepsis, true informed consent at the time of presentation to the ED is not feasible. Caregivers will be approached by the research team at a later time to provide deferred consent. This model has been used in previous sepsis studies at PERC sites.