PLUS - Plasma-Lyte 148® versUs Saline Study

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THE GEORGE INSTITUTE
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Facts

- Millions of critically ill patients around the world are given normal saline as part of their treatment.
- In Australia, sales of normal saline by Baxter Healthcare were over 6.1 million units in 2013 compared with only 207,000 units of Plasma-Lyte 148®.
- Preliminary data suggest use of Plasma-Lyte 148® may reduce relative risk of death for critically ill patients by 12.5%.

Background:

- Fluid resuscitation is a fundamental component of the management of critically ill patients and the choice of fluid is a longstanding issue of debate.
- Worldwide, 0.9% saline ("normal saline") has traditionally been the most widely used resuscitation fluid, however its use is increasingly challenged by emerging evidence that its high chloride content may have clinically important adverse effects.
- Use of balanced crystalloid solutions such as Plasma-Lyte 148® may be associated with decreased mortality and decreased risk of acute kidney injury.

Aims:

- Primary: To determine whether fluid resuscitation and therapy with a "balanced" crystalloid solution (Plasma-Lyte 148®) decreases 90-day mortality in critically ill patients requiring fluid resuscitation when compared with the same treatment using normal saline.
- Secondary: To determine whether fluid resuscitation and therapy with Plasma-Lyte 148® decreases the risk of acute kidney injury and other adverse effects and to examine health economic outcomes.

Methods:

- PLUS is a multi-centred, binational (Australia and New Zealand) randomised controlled trial that will enrol 8,800 patients at approximately 40 study sites.
- Participants will be patients expected to be treated in the Intensive Care Unit (ICU) for three days or more. They will be randomly assigned to receive either Plasma-Lyte 148® or normal saline for all resuscitation episodes and for all compatible crystalloid therapy while in ICU.

Partners:

Australian and New Zealand Intensive Care Society Clinical Trials Group

Medical Research Institute of New Zealand (TBC)

Supporters:

National Health and Medical Research Council, (NHMRC) Australia

Baxter Healthcare

Impact:

- PLUS is a pivotal trial that will provide an accurate and reliable estimate of the comparative risks versus benefit of Plasma-Lyte 148® versus normal saline.
- As the only definitive trial comparing normal saline with a balanced solution, PLUS will influence clinical practice guidelines and clinical practice worldwide and will affect the health of millions of acute and critically ill people.

Contact

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The George Institute For Global Health

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