

The TARGET Trial

A nutrition study researching nutrition therapy for ICU patients by Monash University

TARGET - The Augmented versus Routine approach to Giving Energy trial

The importance of nutrition in critical illness is widely recognised, yet there remains uncertainty about the optimal target for caloric requirements.

The TARGET trial is a pivotal, 4000-patient, multi-centre, double-blinded, randomised, controlled, parallel-group, phase III clinical trial. Its aim is to determine if the delivery of more calories improves survival in critically ill patients who are mechanically ventilated and remain in intensive care for more than a few days. The nutrition is delivered using energy dense, enteral nutrition and studies their survival rate over 90 days when compared to routine care.

Trial structure and strategy

TARGET involves 46 ICU's in both New Zealand and Australia. The trial commenced in 2016 and enrolment will be complete in January 2018. The primary outcome is survival at day 90 – due in April 2018 and then the six month follow-up will provide full results of functional outcomes in January 2019

The project team has developed a simple and inexpensive strategy to deliver more calories safely and effectively via the enteral route. The strategy is to substitute standard formula (1.0 kcal/ml) with energy dense formula (1.5 kcal/ml) and deliver it at the same rate. This is a novel concept. Concentrated feed formulae are used in ICU feeding practice but are usually given at a reduced rate to patients who require fluid restriction. This is the first time that a concentrated formula has intentionally been given at full rate with the aim of increasing calorie delivery and in the knowledge that over a 24 hour period the full target volume of feed is rarely given.

Secondary endpoints include:

- survival to hospital discharge, 28 days, & six months.
- length of stay in ICU and hospital.
- ventilator free days.
- dialysis free days.
- inotrope free days.
- all to day 28, functional outcomes at 180 days (SF 36, EQ-5D-5L).



“

Spinnaker manages drug and study treatment movements from warehouse orders, through hospital logistics, to patient allocation and finally reconciliation. We worked closely with the project manager on TARGET to make Spinnaker “fit” her way of working, with the ultimate aim of tracking everything AND keeping her teams workload manageable. A great trial takes more than smart technology, it takes genuine resourceful thinking right from the early conception through to final analysis.”

”

Audrey - CEO Spiral

Friendly interface streamlines data collection

As Monash University had not used an online inventory management system before they looked to previous trials with other institutions, for recommendations. Lorraine Little, Senior Project Manager for TARGET says,

“We had not used Spiral before but we knew that they had done the SuppPN trial which was a very useful reference for us. When we talked to their Project Manager about Spirals’ Spinnaker software, they said it was really easy to use, the website had an intuitive user interface and was completely reliable”.

Lorraine also knew that Spiral’s software had been used successfully on the HEAT trial and the Split Study. She says,

“In our industry word of mouth is very important and getting positive feedback about Spiral from both sides of the Tasman was really encouraging. The TARGET trial is a big trial with many people using the database. It required very intuitive, logical solutions and simple, clear instructions. Nutrition data is also particularly difficult with the challenge of getting the definition completely correct.”

Inventory management made easy with an online solution

With over 100,000 bags of study treatment in this double-blind trial some smart stock management was needed. All study treatment bags look the same and patient allocation is purely by bag number. Trying to manage such a large database manually is just not feasible. Lorraine Little says,

“Inventory was our biggest concern but with Spinnaker this is managed very easily”,

Genuine support coupled with innovative software development

The Spinnaker product has a strong reputation as a very robust, adaptable study management software and when asked about using Spinnaker for the TARGET study Lorraine said,

“Although their technical expertise has proven to be excellent, it is their customer service and problem solving skills that came to fore as soon as we got underway. We can tell them what we want but we are not programmers so we have no idea how to achieve it. We also don’t know what is possible. Audrey and Cain are excellent at listening to us and coming back with very good solutions. Even when we changed the data sets there was no fuss and it was, “yes we can do that and this is how we will manage it”. And when you see what they come up with you think “oh I wish I had thought of that!””

[Read more about the TARGET Study online »](#)



Lorraine Little

Senior Project Manager
for TARGET

The
TARGET
Trial
[more information](#)