



The Augmented versus Routine approach to Giving Energy Trial

Setup

- Sites will start in 2016
- RACE Feasibility study will begin soon



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Progress

- ◆ **Health Research Council, New Zealand** awarded \$1.2mil NZD.
- ◆ **Supplier for feeds** are not locked in but we are getting closer to agreement. Fresenius Kabi (FK) is the front runner.
- ◆ Our study will be presented to the **FK Global Trials Committee** this month. We are expecting approval and will be notified by the end of August.
- ◆ Once the study feed **supplier is confirmed** we can then progress to finalising logistics and protocol; and commence the ethics submissions.
- ◆ **Agreement process** to begin when Fresenius Kabi confirm they will supply feed (planning for success).
- ◆ **AQIST permit** to be completed and submitted to the Department of Agriculture.
- ◆ **CRF** is being finalised.
- ◆ **Database development** well advanced for CRF (but not inventory).
- ◆ **Data** will be hosted on the new Spiral server in Sydney (data was to be hosted in Auckland).
- ◆ **Clinical Trial Agreement Schedule 4** Special Considerations application to SEBS; awaiting approval.
- ◆ **RACE Feasibility study** which aims to identify outcomes of interest for longitudinal studies is on track to be conducted at four sites pending ethics approval.

The log-in page for our database looks like this:

Get in touch with us at Spiral if you would like to see more of our software spinnaker@spiral.co.nz

About the Target Study

TARGET - The Augmented versus Routine approach to Giving Energy Trial. TARGET is a 4,000 patient, multicentre, double-blinded, randomised, controlled, parallel-group, phase III clinical trial. The primary aim of the study is to determine if augmentation of calorie delivery using energy dense enteral nutrition in mechanically ventilated patients improves 90 day survival when compared to routine care. A secondary aim is to determine if augmentation of calorie delivery using energy dense enteral nutrition in mechanically ventilated patients improved functional outcomes at 180 days when compared to routine care. Eligible patients will be randomised 1:1 to receive TARGET protocol enteral nutrition (EN) formulation of either 1 kcal/ml or 1.5 kcal/ml. Protein content in both TARGET protocol EN formulations will be similar.

TARGET protocol EN will be administered for up to 28 days during the ICU stay.