

Issue **1**
April 2015



TARGET
Nutrition Study

Newsletter

The Augmented versus Routine approach to Giving Energy Trial

Starting

- October 2015— 7 vanguard sites
- December 2015—5 more sites
- March 2016—all sites

Progress

- **NHMRC grant** \$3.5mil AUD
- **Application NZ HRC Grant** \$1.2mil NZD to be advised July 2015
- **CTG** endorsement obtained
- **Management Committee** selected
- **Project Managers** appointed
- **Protocol V1 dated 3 Dec 2014**
 - ◆ RAH approved under NMA for QLD, NSW, VIC & SA
 - ◆ NZ HREC pending
- **Protocol V2** to be finalised and sent to ACT, WA, TAS & NT for submission
- **Protocol EN** contract not yet awarded; details to be finalised
- **DSMC Chair** Professor Deborah Cook
- **Site Expression of Interest conducted:**
 - ◆ 39 Australia ◆ 11 New Zealand
- **Data Management**
 - ◆ Web development—Spiral Software
 - ◆ CRF data points being finalised
- **Study Registration** ClinicalTrials.gov # NCT02306746



Contact Details

Project Manager:

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Study Design

A 4,000 patient, multicentre, double-blinded, randomised, controlled, parallel-group, phase III clinical trial conducted in adult ICUs in Australia and New Zealand

Hypothesis

Primary: in mechanically ventilated patients, the enteral delivery of energy dense nutrition improves 90 day survival when compared to standard enteral care (which usually results in under-nutrition)

Secondary: that enteral delivery of energy dense nutrition will also improve functional outcomes

Outcomes

Primary: all-cause mortality at 90 days

Secondary:

- Death at ICU and hospital discharge, 28 days and 180 days
- Duration of survival from randomisation
- Duration of ICU and hospital stay
- Ventilator-free, dialysis-free and vasopressor-free days to day 28
- Functional outcomes at 180 days

Eligible patients will be randomised to receive:

1.5 kcal/ml Protocol EN

Or

1.0 kcal/ml Protocol EN

TARGET protocol EN will be administered for up to 28 days unless EN is ceased before Day 28 (or until the patient dies or leaves ICU).

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Is the patient ≥ 18 years of age?
2. Is the patient intubated and receiving mechanical ventilation?
3. Has the patient commenced or are they about to commence enteral nutrition?
4. Is the patient expected to receive EN at least until the day after tomorrow?

Exclusion Criteria

1. Any Enteral or Parenteral Nutrition received for >12 hours in this ICU admission
2. Previously enrolled in this study
3. Treating clinician considers the EN goal rate (i.e. 1ml/kg of ideal body weight per hour) to be clinically contraindicated e.g. requirement for fluid restriction
4. Requirement for specific nutritional therapy as determined by the treating doctor or dietitian i.e. TARGET protocol EN not considered to be in the best interest of the subject
5. $\geq 15\%$ burns
6. Death is deemed to be imminent or inevitable during this admission and either the attending physician, patient or substitute decision maker is not committed to active treatment
7. The patient has an underlying disease that makes survival to 90 days unlikely



Marianne Chapman



Sandra Peake

TARGET Management Team

- ◇ **Co-Chair:** Marianne Chapman
- ◇ **Co-Chair:** Sandra Peake
- ◇ **Project Manager:** Lorraine Little /
- ◇ **Project Manager:** Diane Mackle

Management Committee

Rinaldo Bellomo
 Adam Deane
 Michael Horowitz
 Stephanie O'Connor
 Emma Ridley
 Patricia Williams
 Andrew Davies
 Suzie Ferrie
 Kylie Lange
 Jeffrey Presneill
 Frank Van Haren
 Paul Young

Working Party

Rinaldo Bellomo
 Adam Deane
 Stephanie O'Connor
 Emma Ridley
 Patricia Williams
 Andrew Davies
 Jeffrey Presneill
 Paul Young

Timeline

Protocol v2 finalised	Apr 2015
HREC submissions Protocol v2	Apr 2015
CRF completed	April 2015
Database tested & ready	Aug 2015
State investigator meetings	Sept 2015
All sites started	Mar 2016
Enrol 2,000 patients 1st Interim Analysis	Sep 2017
Recruitment completed	Mar 2019
180 day follow up of 100% completed	Sep 2019
Manuscript submitted	Nov 2019





TARGET Sites...Confirmed/Considering/Expressed Interest

AUSTRALIA

ACT

Canberra Hospital**

QLD

Princess Alexandra Hosp

Royal Brisbane Hospital

Toowoomba Hospital

Mater Private Hospital

Mater Public Hospital

WA

Bunbury Hospital

Fiona Stanley Hospital

Joondalup Hospital

Royal Perth Hospital

Sir Charles Gairdner Hosp

NT

Alice Springs Hospital

NSW

John Hunter Hospital

Royal Prince Alfred Hosp**

Royal North Shore Hosp**

St Vincent's Hospital Syd

St George Hospital

Calvary Mater Hospital

Newcastle

Gosford Hospital

St Vincent's Hospital Syd

Sydney Adventist Hosp

Concord Hospital

SA

The Queen Elizabeth**

Royal Adelaide Hospital**

Lyell McEwin Hospital

VIC

Austin Hospital**

Bendigo Hospital

Footscray Hospital

Geelong Hospital

The Northern Hospital

Royal Melbourne Hosp

St Vincent's Hospital Mel

Sunshine Hospital

Box Hill Hospital

Maroondah Hospital

The Alfred

Monash Medical Centre

Knox Private Hospital

TAS

Royal Hobart Hospital

NEW ZEALAND

Auck Hospital CVICU

Auck Hospital DCCM

Middlemore Hospital

North Shore Hospital

Rotorua Hospital

Tauranga Hospital

Hawkes Bay

Hutt Valley Hospital

Wellington Hospital**

Nelson Hospital

Christchurch Hospital

**vanguard sites