The Early Nasojejunal Tube To Meet Energy Requirements In Intensive Care Study (The ENTERIC Study)

A multi-centre randomised controlled trial comparing early jejunal feeding (using a frictional nasojejunal tube) and standard feeding in critical illness.

Andrew Davies, Rinaldo Bellomo, Jamie Cooper, Gordon Doig, Simon Finfer, Daren Heyland and Siouxzy Morrison, for the ANZICS CTG

Background: In critically ill patients, artificial nutritional support is now considered to be the standard of care as it improves wound healing, reduces complication rates and improves clinical outcomes. Current guidelines suggest that enteral nutrition (EN) should be preferred to parenteral nutrition, and that it should be commenced early after admission. A recent clinical trial demonstrated that improvements in the proportion of nutritional support delivered to ICU patients led to reduced hospital length of stay and mortality. EN is usually given via a nasogastric tube (NG) and whilst this is tolerated in most patients, a moderate proportion of ICU patients (up to 46%) develop the syndrome of upper gastrointestinal intolerance (high gastric residual volumes or vomiting) which increases the risk of inadequate nutritional support, pneumonia and mortality. Small bowel feeding (using a nasojejunal tube) bypasses the dysfunctional stomach and has been compared to gastric feeding in a number of ICU patient studies. Whilst some studies have shown that small bowel feeding leads to improved nutritional outcomes, none have individually detected significantly improved clinically meaningful outcomes. A meta-analysis which aggregated these study results found that small bowel feeding is associated with a significantly reduced rate of pneumonia although a second meta-analysis was not as conclusive. Nasojejunal (NJ) tubes are uncommonly used in current Australasian clinical practice, most likely because of the technical and logistical difficulties associated with their placement. The recently developed frictional NJ tube appears to offer simplicity and adequate success rates of placement into the jejunum. There is a strong rationale to ascertain in an adequately powered study whether jejunal feeding reduces pneumonia incidence, hospital length of stay and costs when compared to standard feeding strategies. Prior to this, we aim to determine whether early jejunal feeding (using a frictional NJ tube) increases the energy delivered to ICU patients when compared to standard feeding (commencing through a NG tube).

Objectives: The primary objective of the study is to establish whether early jejunal feeding (using a frictional NJ tube) increases the amount of EN delivered during ICU admission (which will be calculated as a proportion of predicted energy requirements) in mechanically-ventilated, medical-surgical critically ill patients with reduced gastric motility when compared to standard feeding (commencing through a NG tube).

Secondary objectives are to compare the effects of both feeding strategies on other clinical outcomes and to examine success and complication rates of the frictional NJ tube.

Design: Prospective, multi-centre, concealed, stratified, randomised, clinical trial.

Inclusion criteria: ICU patients ≥ 16 years old; and who have been in ICU ≤ 72 hours; and who are receiving mechanical ventilation with an anticipated need for > 48 hours of mechanical ventilation; and who are receiving a continuous narcotic infusion; and who have *either* a single gastric residual volume ≥ 150 mls *or* nasogastric drainage ≥ 500 mls over 12 hours.

Exclusion criteria: Patients admitted to ICU following previous or recent upper GIT surgery; known gastric malignancy; known oesophageal varices; current peptic ulceration; current mechanical bowel obstruction; current gastrostomy, jejunostomy or surgically-placed tube; contraindication to the use of the nose and mouth for enteral tube insertion; receiving nutritional support prior to ICU admission; severe coagulopathy; pregnancy; brain death; expected death within the next 24 hours; admission following cardiac arrest with suspected hypoxic-ischaemic encephalopathy; previous participation in this study; clinicians believe EN is contra-indicated.

Methods: 180 patients will be centrally randomised to receive either early jejunal feeding or standard feeding. Patients allocated to early jejunal feeding will have a frictional NJ tube inserted to commence EN, and patients allocated to standard feeding will have EN commenced through a NG tube. Clinical staff will follow protocols for nutritional support and diagnosis of ventilator-associated pneumonia (VAP). Whilst blinding is not possible for all outcome assessments, the VAP rate used for comparisons between feeding strategies will be diagnosed by a blinded adjudication committee.

Outcomes: The primary outcome for the study is the amount of EN delivered (calculated as a proportion of predicted energy requirements). Secondary outcomes include amount of EN delivered during the first 10 days, daily cumulative proportion of EN delivered during the study, ventilator-associated pneumonia rate, duration of mechanical ventilation, duration of hospitalisation, hospital mortality, as well as the success and complication rates of the fictional NJ tube.

Relevance: Results of this study will provide important nutritional outcome information regarding early jejunal feeding and will also provide logistical and safety data regarding the frictional NJ tube. Whilst the primary outcome (amount of EN delivered) is a surrogate outcome, it is an outcome that has been previously demonstrated to translate into improvements in clinically-meaningful outcomes. This study should also provide key data for sample size calculations of a study designed to test whether early jejunal feeding reduces pneumonia rate.