calories

(Early nutritional support in the critically ill)

Background

Malnutrition remains a common problem in critically ill patients. The consequence of malnutrition includes vulnerability to complications, such as infection. Early nutritional support is recommended to address both deficiencies in nutritional state and related disorders in metabolism.

However, evidence is conflicting regarding the optimum route of delivery. Is nutritional support via the parenteral route better than the enteral route?

Parenteral versus enteral route

The enteral route (EN) is the mainstay of nutritional support in critical care but it is frequently associated with gastrointestinal intolerance and underfeeding. The parenteral route (PN), though more invasive and expensive, is more likely to secure delivery of the intended nutrition. However, historically, PN has been associated with more risks and complications. Recent improvements in the delivery, formulation and monitoring of PN justify further comparison and evaluation of these nutritional support techniques, particularly in the early phase of illness.

Despite three meta-analyses, the use of PN in critical care remains controversial and existing research studies confuse route (PN versus EN) with timing.

In late 2007, in view of the conflicting evidence, the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme put out a call for a large, pragmatic, randomised controlled trial to be conducted to determine the optimal route of early nutritional support in critically ill patients.

What is CALORIES?

A pragmatic, open, multicentre randomised controlled trial comparing early nutritional support via the parenteral versus the enteral route

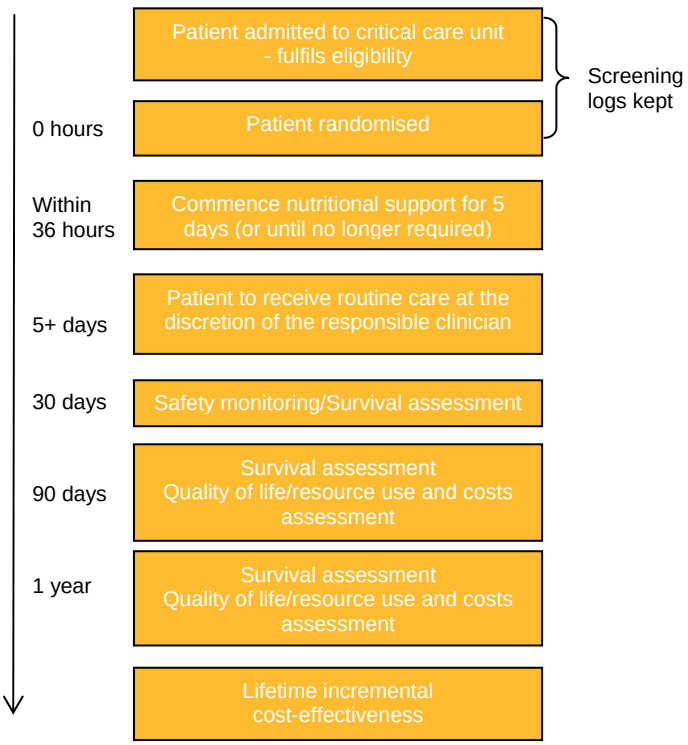
Primary objectives

- To estimate the effect of early nutritional support via PN, compared with EN, on mortality at 30-days.
- To compare the incremental cost-effectiveness, at one year of early PN, versus early EN.

Sites/Patients

- **20 units**
  (adult general critical care units)
- **2400 patients**
  (1200 per arm – equating to 60 patients, per hospital, per year)

Timeline



Screening/Eligibility

Patients who either on, or soon after admission, (but within a timeframe to consent and randomise within 36 hours of the date/time of original critical care unit admission in your hospital), are:

- adult (defined as age 18 years or over);
- an unplanned admission (including planned admissions becoming unplanned, e.g. unexpected post-operative complications);
- expected to receive nutritional support for two or more days in your unit;
- not planned to be discharged within three days from your unit defined by clinical judgment.

Randomisation

Patients will be randomised to receive early nutritional support via the parenteral or enteral route. Nutritional support should commence within 36 hours of admission to the unit and continue for five days (120 hours) with the ability to transition to oral feeding earlier (as per clinical judgement).

Funding

Central

- NIHR HTA Programme (07/52/03)

Local

- NIHR CRN Portfolio Trial
  - Portfolio Number: 10098
  - CSP Number: 22078
- NHS Support Costs negotiated equivalent to:
  0.1 WTE Critical Care Consultant
  0.5 WTE Research Nurse (Band 7)
  0.1 WTE Dietician (Band 7)
  1.4 hours/week Pharmacist (Band 6)

Sponsor

ICNARC

Trial Management

ICNARC Clinical Trials Unit

Team

Chief Investigator
Kathy Rowan (ICNARC, London)

Clinical Chief Investigator
Michael Mythen (University College Hospital)

Trial Manager
Blair McLennan (ICNARC, London)

Data Manager
Jermaine Tan (ICNARC, London)

CTU Manager
Sheila Harvey (ICNARC, London)

Trial Statistician
Francesca Parrott (ICNARC, London)

Senior Statistician
David Harrison (ICNARC, London)

Health Economist
Richard Grieve (LSHTM, London)

Clinical co-investigators
Richard Beale (St. Thomas' Hospital)
Geoff Bellingan (University College Hospital)
Richard Leonard (St. Mary's Hospital, London)

For further information

Email calories@icnarc.org
Tel 020 7269 9277
Fax 020 7831 6879

ICNARC
Napier House
24 High Holborn
London
WC1V 6AZ