calories Newsletter Issue 3, January 2012

Aim and rationale

It is not clear which is the optimum route for delivery of early nutritional support to critically ill patients. The purpose of CALORIES therefore, is to compare the clinical and cost-effectiveness of early nutritional support via the parenteral route versus the enteral route. Following randomisation, nutritional support should start as soon as possible (no later than 36 hours following critical care unit admission) and continue for five days (120 hours), or until the patient transitions to exclusive oral feeding or is discharged from the critical care unit. Patients allocated to the parenteral route arm must <u>not</u> receive enteral trickle feeding during the five days.

New sites



to...

Dorset County Hospital & Kettering General Hospital

...who have recently opened to recruitment

Monthly teleconference

Next teleconference is 26 January 2012

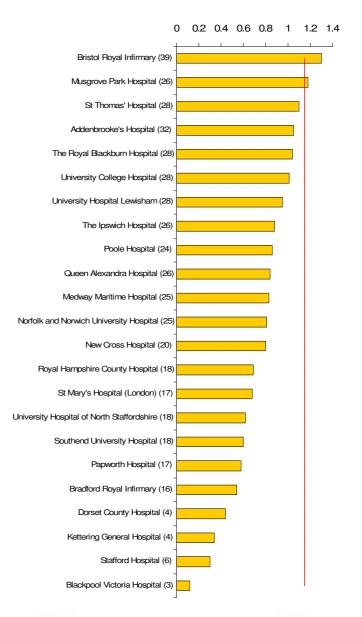
This is open to all CALORIES Team members at participating sites and provides an opportunity to ask questions or discuss any aspect of the trial with the CALORIES Team at ICNARC and to share experiences of the trial with other sites. We strongly encourage you to participate in these teleconferences.



476 patients recruited

Congratulations to **Bristol Royal Infirmary** who lead the way with 39 patients!

We need 2400 patients over two years. This equates to an average of 5 patients per site per month, or 1.15 patients per site per week.



Well done to... Bristol Royal Infirmary Musgrove Park Hospital

...who are currently above the target recruitment rate! Keep up the good work!

CALORIES: a multi-centre randomised, controlled trial comparing the clinical and cost-effectiveness of early nutritional support in critically ill patients via the parenteral versus the enteral route NIHR HTA grant: 07/52/03 Portfolio ID: 10098





Q. For baseline Glasgow Coma Score (GCS), if a patient is sedated for all of the 24 hours prior to randomisation, what should be recorded for the GCS?

A. If no value is available for the 24 hours prior to randomisation, record the baseline GCS as 'NR'.

Q. Which patients should be recorded on the Screening Log for CALORIES?

A. Record all eligible patients (i.e. met all inclusion criteria but no exclusion criteria) who were not randomised, and all patients who met all inclusion criteria plus one or more of the exclusion criteria.

Q. For patients in the enteral route arm, should "free drainage" be included in the volume of aspirates?

A. Yes, please include this in the aspirates volume and write a note in the comments box indicating the volume of "free drainage" and the volume aspirated.

Q. Should vasoactives, other than those listed in the Case Report Form (CRF), be recorded?

A. Yes, please record the name and maximum dose in the Interventions box, and record in the Comments box on the web portal.



Delegation Log and Trial Contacts Form

Please ensure these are kept up-to-date. Copies should be sent to ICNARC and the originals filed in the Investigator Site File.

Feed products

If you are using any enteral or parenteral feed products that are not listed on the web portal, email <u>calories@icnarc.org</u> with the full name of the feed product to have them added.



Thank you for your continued commitment to the CALORIES Trial

Timely data entry

Please ensure that data are entered onto the CALORIES Web Portal as soon as possible. The 'Baseline – Contact details' page should be completed soon after randomisation as we need to inform the patient's GP of their participation in the CALORIES Trial within a week of randomisation.

Retrospective consent

Retrospective consent should be obtained from the patient as soon as possible after they regain mental capacity, while the patient is still in hospital. Please inform the CALORIES Team at ICNARC if a patient regains mental capacity and is discharged from hospital before retrospective consent could be obtained.



Clinical support line 24/7

A CALORIES Investigator is available 24/7 for advice and support. If you don't get an answer when you call, please leave a message, including your name and telephone number. Your call will be returned as soon as possible.

Contact us

ICNARC CALORIES Team, general enquiries

Email: calories@icnarc.org Tel: 020 7554 9784 Fax: 020 7388 3759

CALORIES 24/7 clinical support line Tel: 020 7554 9775

SAE reporting to ICNARC

Fax: 020 7388 3759



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