

calories Newsletter

Issue 7, April 2013

Less than one-third to go...!

Over 1600 patients recruited...

... we are now over two-thirds of the way to our target of 2400 patients!

Over the last few months recruitment has averaged 95 patients per month, with record number of patients recruited in December 2012 and January 2013. If we continue at this rate, we will complete patient recruitment by the end of the year.

Thank you for your continued support!

CALORIES Top Ten

Well done to the top ten recruiting sites between December 2012 and February 2013.



The Royal Blackburn Hospital	21
St Mary's Hospital London	20
St Thomas' Hospital	20
Bristol Royal Infirmary	19
Queen Alexandra Hospital	18
Addenbrooke's Hospital	17
The Ipswich Hospital	17
The Queen Elizabeth Hospital, King's Lynn	14
University College Hospital	13
University Hospital of North Staffordshire	13

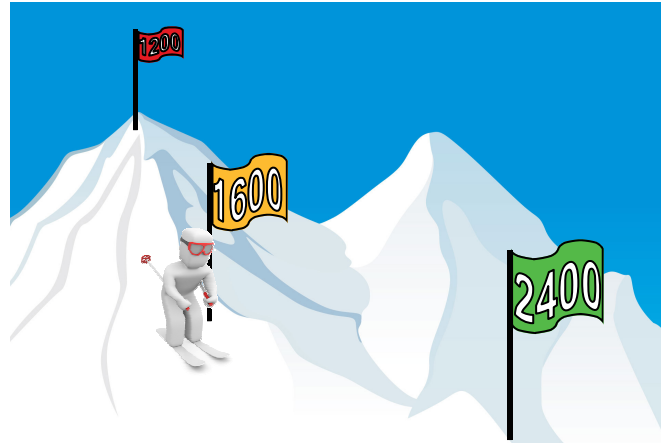
Congratulations to The Royal Blackburn Hospital who top the list with 21 patients!

Welcome to...

St Richard's Hospital

...who have recently opened to recruitment.

We now have 25 sites open and recruiting!



Goodbye to Rachael

We were sad to say goodbye to Rachael last month. We would like to thank her for all her hard work as Trial Manager on CALORIES, and wish her all the best in her new job!



Collaborators' Meeting

Thank you to all those who attended the Collaborators' Meeting on 17 January 2013. We hope you enjoyed the meeting and picked up some new and helpful tips!



CMP data

Remember, Case Mix Programme (CMP) data forms part of the CALORIES dataset. It is important to ensure that your unit is actively participating in the CMP. Active participation is defined as:

- submitting data no later than six weeks after each quarter period;
- returning corrected Data Validation Reports (DVR) no later than six weeks after date of receipt.

If you have any queries about CMP data at your site, please email calories@icnarc.org.

Informed consent

If at the time of randomisation, a patient is known to have a pre-existing condition (i.e. not related to their critical illness) that would definitely prevent them from being able to provide informed consent following recovery from their critical illness, it is advised they are not recruited into the trial. Any patients excluded for this reason should be recorded on the Screening Log.

Full information about the patient's mental capacity may not be available at the time of randomisation. If, following randomisation, it becomes apparent that a patient will not be able to provide informed consent, please write a File Note and add a Comment on the web portal.

Adverse Events



Specified: Please indicate, in the Case Report Form (CRF) and on the web portal, whether or not any of the specified adverse events (AE) listed on pages 37-38 of the CRF occurred between randomisation and 30 days post-randomisation. If a specified event(s) did not occur, "0" (i.e. None) should be entered under "Severity". If a specified AE did occur, please provide details of the event requested in the CRF.

Other: Any other AEs that occur between randomisation and 30 days post-randomisation should be recorded. An AE is defined as:

Any untoward medical occurrence or effect in a patient treated on a trial protocol, which does not necessarily have a causal relationship with trial treatment. An AE can therefore be any unfavourable symptom or disease temporally associated with the use of the trial treatment, whether or not it is related to the trial treatment.

AEs that occur as a result of the patient's medical condition or standard treatment do not need to be recorded. If there is any uncertainty about an AE's association with the trial treatment, then it should be recorded.

Dates for diary



Monthly teleconference

16 April 2013, 13.00 - 14.00

Open to everyone, please dial-in and join us

The 16th Annual Meeting of the Case Mix Programme

18 April 2013

The Mermaid Conference and Events Centre, London
There will be a CTU stand, so come and say hello!

UK Critical Care Research Forum Meeting

4 - 5 July 2013

King's College London

Musgrove Park Site Team



Team: Dawn Bayford, Angela Walsh, Trish Doble and Pippa Richards

Site: Musgrove Park Hospital

What do you enjoy most about your roles?

We are fortunate to be a team of four part-time nurses able to offer seven-days a week cover for the CALORIES Trial. We also work in either ITU or Critical Care Outreach. We are often able to screen patients in our dual roles and provide continuity when patients are transferred to a ward which has given us much job satisfaction.

I hear you ask "is it not difficult to keep up to date with everything if you are all part-time?" All we can say is it seems to work well for us! Communication could potentially be a challenge but we all commit to keeping file notes, a communication book with daily entries and regular team meetings.

How do you, as a team, ensure awareness is maintained for CALORIES at your site?

Staff across our organisation are used to us popping in to spread the word about our trials and this has helped to promote the work our Critical Care Research Team is doing.

What is the best piece of advice you have for other research teams working on the CALORIES Trial?

Without exception everyone in the ITU team thinks about CALORIES from the point of admission and this has made our job a lot easier. All those days of being visible as a Research Nurse and screening every patient have really paid off!

Contact us

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