

New sites



to...

Furness General Hospital

&

The Queen Elizabeth Hospital, King's Lynn

...who opened to recruitment last month

We now have 25 sites open and recruiting!

Farewell to Louise

We were very sad to say farewell to Louise last month. We would like to thank Louise for her commitment and enthusiasm, and for all her hard work on CALORIES. We wish her all the very best in her new job!

Rachael Scott has taken over management of the CALORIES Trial.

Screening Logs

Please ensure that your Screening Logs are kept up-to-date, as we will be requesting copies of these quarterly. Next request will be in May!

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

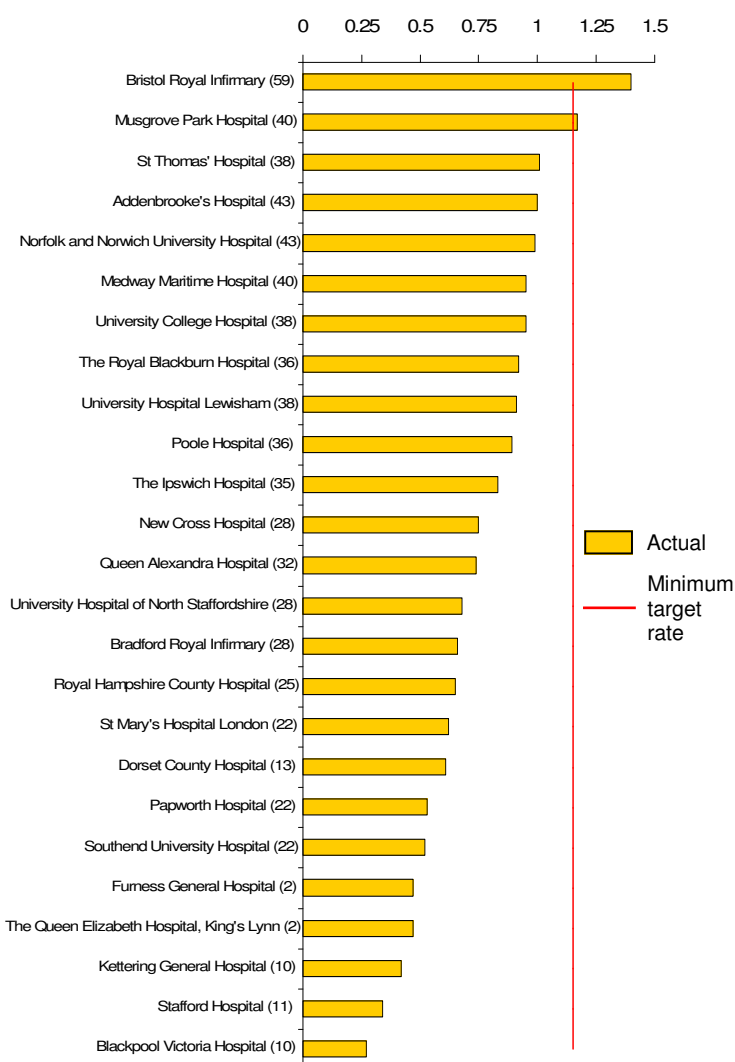
Date for your calendar



701 patients recruited

Congratulations to **Bristol Royal Infirmary** who lead the way with 59 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 minimum target recruitment rate.

However, there are many more sites not far behind!



Keep up the good work!



Focus on data

Malnutrition status

Please don't forget to record the ulna length, mid-upper arm circumference (MUAC) and extent of oedema at the time of randomisation (see Randomisation/Minimisation criteria page of the Case Report Form (CRF)).

Safety monitoring

Please indicate on the 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. If a specified AE *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.

Any other AEs that occur between randomisation and 30 days — i.e. an event that is cause for concern or is felt to be associated with participation in the trial should also be recorded on the CRF and on the web portal.

Please contact the CALORIES Team if you require further guidance.

Withdrawals

If a patient/consultee withdraws consent/agreement, data should be collected up to the point of withdrawal. This is in line with National Research Ethics Service guidelines.

Patients who do not receive their randomly allocated treatment (for whatever reason) must remain in the trial and continue with follow-up as per the trial protocol. They cannot be withdrawn. Please provide details in the Comments box on the CRF and on the web portal.

Consultee agreement

If agreement for a patient to participate in the CALORIES Trial is obtained from a Professional Consultee, the next-of-kin (where appropriate) should be informed that the patient is participating in the CALORIES Trial. Please make a note in the Comments box on the Retrospective Consent page of the CRF once the next-of-kin has been informed or indicate that there is no next-of-kin, as appropriate.



Thank you for your continued
commitment to the
CALORIES Trial

Message from the Data Manager — Jermaine Tan

Online Data Validation will be going live soon! This system, built into the web portal, will help identify missing, unusual and invalid data, allowing you to check and complete data validation in real time.



I will be sending guidance to all sites prior to the launch. Looking forward to working closely with you when this validation process begins.

Monthly teleconference

Next teleconference is **14 May 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.

If you have any issues to raise please email them in advance to calories@icnarc.org.



24/7 clinical support line

020 7554 9774

Don't forget there is a trial investigator available 24/7 to answer any questions about patient eligibility, randomisation etc.

