

ProMISe Newsletter

Issue 8, April 2013

Come and meet the Merry Men!

Collaborators' Meeting details:

Date: Thursday 30 May 2013
Time: 10.30 – 15.30
Venue: University College London

Please come and join us (including ProMISe's clinical co-investigators – the Merry Men!), link up with teams from other sites and find out what "Maid Marian" recruit!

The programme will include: an update on ProMISe; small group discussions to share ideas and best practice for running the trial locally; and plenty more...!

Please complete the registration form and return it to promise@icnarc.org as soon as possible.

We have set a challenge...

Greetings...

... to the following sites who have recently opened to recruitment on ProMISe:



We now have **50** sites open!

Compliance

It is vital to ensure that the six-hour, early goal-directed, resuscitation protocol is fully complied with, including:

- the PreSep catheter is inserted and delays in insertion are kept to a minimum
- physiology is monitored throughout the protocol and recorded hourly on the Case Report Form (CRF)
- interventions are delivered when indicated by the protocol

If any part of the resuscitation protocol was not complied with, please feedback specific issues to your team to ensure future patients are fully compliant.

Collaborators' Meeting challenge:

Current recruitment: **828** (as of 17 April 2013)
Challenge: **recruit double figures each week**



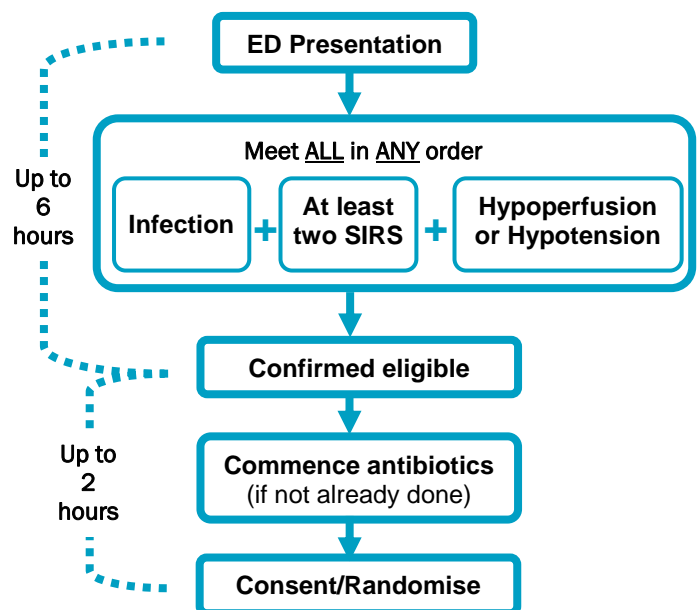
If we meet this challenge by recruiting at least ten patients per week over the next six weeks, we can celebrate having **under 400 patients to go** by the Collaborators' Meeting – there may even be prizes!

Recruitment timings

Patients have to meet **all** inclusion criteria within six hours from presentation at ED.

Once the inclusion criteria is met, you then have a further two hours to consent and randomise the patient.

Randomisation should be completed as soon as possible.



Example case:

Presentation at ED: **12:45** (meet inclusion criteria by 18:45)
All inclusion criteria met: **17:50** (consent/randomise by 19:50)
Patient randomised: **19:10**

Data validation

- ➔ **DVR A queries:** remember to confirm correct data by clicking the orange tick icon on the relevant page on the web portal. This will make the query disappear.
- ➔ **DVR B queries:** please print and sign-off to indicate that missing or unusual data have been checked and are correct. A copy should be sent to the ICNARC CTU and the original should be filed with the patient's paper CRF. The query will remain on the DVR B.



Adverse event reporting

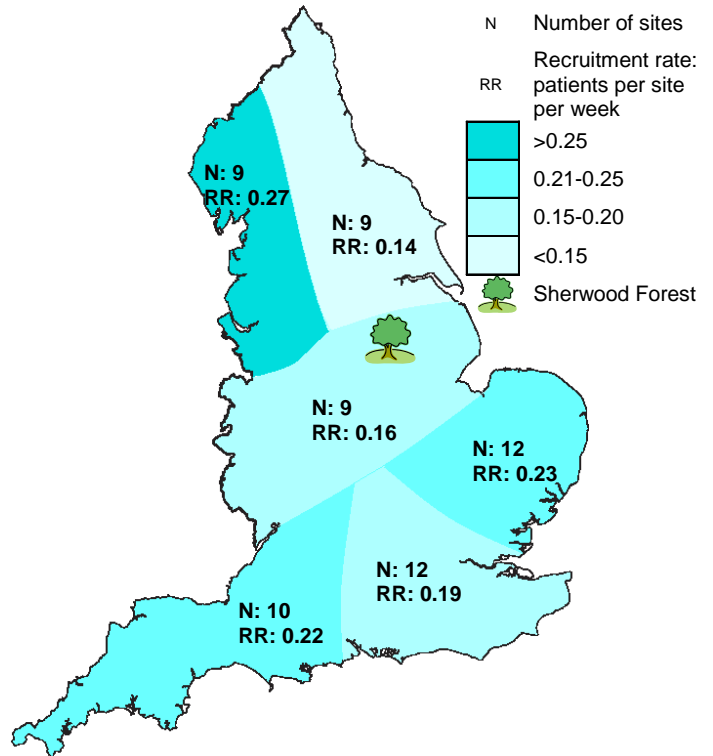
- ➔ Please indicate, in the CRF and on the web portal, whether or not any of the specified adverse events (listed on pages 37-38 of the CRF) occurred between randomisation and 30 days post randomisation. If a specified event(s) did not occur, "0" (i.e. None) should be entered under "Severity".
- ➔ Please ensure you have all the relevant fields complete before faxing a Serious Adverse Event (SAE) form to us.
- ➔ The sections 'Trial Treatment' (page 1) and 'SAE Assessment: Treatment Type' (page 2) on the SAE form should both specify the treatment given as part of the trial.
- ➔ If the SAE is expected as listed on Appendix 4 of the protocol, the event should be entered as "1" (i.e. expected) on the SAE Assessment section of the SAE form.

Dates for your diary

Next Teleconference
25 April 2013, 12:30 – 13:30

UK Critical Care Research Forum
4 – 5 July 2013, King's College London

Regional shoot-out(law)



Congratulations to the North West region, who have both the highest number of patients recruited (188) and at the highest rate of recruitment (0.27 patients per site per week).

Well done to the following sites that have contributed to this feat:

Arrowe Park Hospital, Blackpool Victoria Hospital, Leighton Hospital, Manchester Royal Infirmary, Royal Lancaster Infirmary, Royal Preston Hospital, Salford Royal Hospital, The Royal Blackburn Hospital, and Whiston Hospital.

Thank you to all sites for your continued hard work in making ProMISe a success!

Important contacts

General enquiries/SAE reporting

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

24/7 clinical support line

Tel: 020 7269 9295

Edwards 24/7 technical support line

Tel: 0800 756 0802

