PRISM Newsletter

ISSUE 3, DECEMBER 2016

Welcome to the Christmas 2016 edition of the PRISM trial newsletter. As a result of your hard work we are proud to announce that we have now randomised our 700th patient into the trial. The success of the trial is only because of the dedication and commitment of all of our local investigators, so thank you! We would also like to welcome a number of new sites who have opened since the last newsletter:

- Royal Preston Hospital
- Furness General Hospital
- Medway Maritime Hospital
- King's College Hospital
- GB Morgagni-L Pierantoni Hospital
- A.O.U. Policlinico "P. Giaccone"
- Ospedale San Paolo - Polo Univeristario
- Fondazione IRCCS Policlinico San Matteo
- Arcispedale Sant'Anna
- Queen Alexandra Hospital
- Yeovil District Hospital
- Queen Elizabeth Hospital, King's Lynn

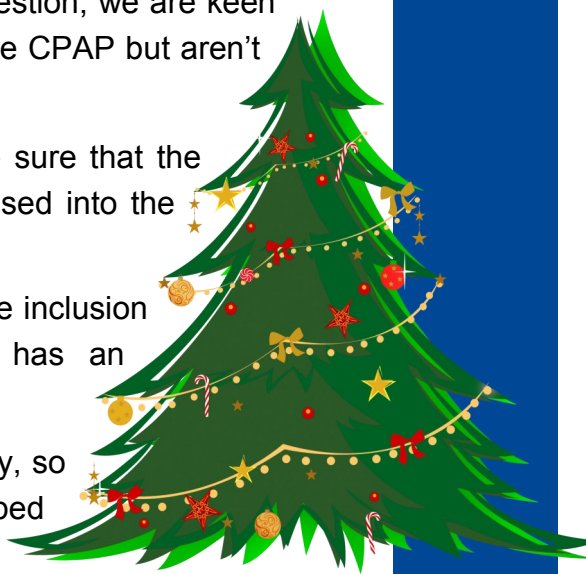
Monitoring

As the recruitment and data collection is now in full swing, we have started conducting monitoring visits at a selection of sites. At these visits we will inspect your site file and conduct source data verification for the first 10 patients up to the 30 day follow up. This will concentrate on the primary outcome, eligibility, consent, randomisation and treatment group allocation. The monitoring visit documents can be found on the website, should you wish to have a look and familiarise yourselves beforehand.

Protocol deviations

Within the constraints of busy clinical services, it is not always possible to fully adhere to the protocol. Thank you to those teams that have let us know about such cases by reporting protocol deviations. In order to best answer the trial question, we are keen to minimise the number of patients that are randomised to receive CPAP but aren't offered CPAP. Here are a few helpful reminders:

- Randomise as late into surgery as possible, once you are sure that the patient can definitely be offered CPAP if they are randomised into the treatment group.
- Before randomising, double check that the patient meets the inclusion criteria, doesn't have any contraindications to CPAP, has an appropriate bed and will be extubated after surgery.
- You can randomise up to four hours after the end of surgery, so if there is a bed delay you should wait to confirm the bed before randomising.



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Top 25 Recruiting sites

Site Name	Total	In Past 30 Days	Data Complete (%)
Oslo University Hospital	120	14	84.8
Sapienza Universita di Roma	63	14	67.3
Leicester Royal Infirmary	51	9	17.9
Royal Gwent Hospital	48	11	58.3
The Royal London Hospital	45	5	87.2
University Hospitals Birmingham	39	3	93.5
Heart of England	38	4	93.9
York Hospital	37	5	100
Antrim Area Hospital	32	9	66.7
Università degli Studi di Sassari	32	6	92
Bradford Teaching Hospitals	31	1	37.9
The Royal Marsden	21	3	43.8
Royal Surrey County Hospital	19	2	100
Royal Alexandra Hospital	18	6	60
Royal Blackburn Hospital	16	6	90
Musgrove Park Hospital	13	6	33.3
The Christie	12	2	100
The Freeman Hospital	11	3	71.4
Arcispedale Sant'Anna	10	9	n/a
Ospedale San Paolo	8	8	n/a
Sunderland Royal Hospital	6	2	100
Stavanger University Hospital	6	0	83.3
Furness General Hospital	5	5	n/a
James Cook University Hospital	5	1	25
Haukeland University Hospital	5	0	0

Fun facts

- Pre-op EQ5D could be completed at the time of taking consent. If there is a prolonged period between signing consent and the surgery for example due to a cancellation, it would be good practice to re-sign consent and redo the EQ5D.
- We would still like you to start CPAP even if more than 4h have elapsed from the surgery and record the total duration of CPAP within 12h on CRF. In these cases we would appreciate if you could record a protocol deviation form.
- All complications for the 30-day follow-up have been defined in the protocol definitions appendix. Investigators completing follow-ups should be familiar with the trial definitions for individual complications. The appendix can be found at the end of the protocol and on our website as a separate document.

Happy holidays!

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