



Newsletter

ISSUE 5, MAY 2017

Welcome to the fifth PRISM trial Newsletter. We are proud to announce that PRISM is now recruiting in over 50 centres across Europe with a few more sites opening soon in South Africa. We are making fantastic progress with more than 1300 patients recruited so far. We would like to welcome the following sites who have opened since the last Newsletter:

- Royal Liverpool University Hospital
- Hospital Universitario Rio Hortega
- Royal Cornwall Hospital
- Nuovo Ospedale Sant'Agostino Estense
- Universitaria Policlinico di Modena
- Ospedale Maggiore Policlinico Milano

Future changes to the protocol

Thanks to all your hard work and efforts the recruitment is going very well, however the intervention compliance is lower than we would like. In order to improve compliance in the CPAP group we are making minor changes to the protocol to clarify existing processes. The changes relate to the timing of randomisation and CPAP delivery. We will contact you directly in the next few months with further details.

One-year follow up

Many sites have now been open for more than a year, and will need to make a start on one year follow up as close to the anniversary of randomisation as possible

Endotracheal re-intubation

The definition for re-intubation for the trial is reinsertion of an endotracheal tube after an intentional removal following completion of the index surgical procedure. Endotracheal re-intubation does not include accidental removal of the endotracheal tube or intubation for a subsequent surgical procedure unless the patient remains intubated after the procedure is completed.

Definitions appendix

When completing the 30-day outcome assessment, if you are not sure of the definitions for the complications please have a look at the protocol definitions appendix which can be found at the end of the protocol and on our website.

Monitoring

We have recently had a wave of monitoring visits and would like to thank the investigators at the following hospitals for their assistance and help during the visits:

- Stavanger University Hospital
- Haukeland University Hospital
- The Christie
- Royal Blackburn Hospital
- Musgrove Park Hospital
- Bradford
- York

After your monitoring visit has been completed you'll receive a report outlining the findings and recommended actions. Once you have resolved our queries please send us a copy of the updated report for sign-off. Do let us know if you need any help with this.

★ In the small number of cases where a patient in the intervention group does not receive CPAP or receives less than four hours, we would appreciate if you could fill in a protocol deviation form on the database as well as on paper. This gives us a valuable insight into the problems you come across when delivering the trial intervention.

★ We would like to add more photos in the future issues of the newsletter. Please send us trial related photos to admin@prismtrial.org

One of the best ways to keep up to date with the trial news is on Twitter: [@prismtrial](https://twitter.com/prismtrial)



Top 40 recruiting sites

Site Name	Total	Last 30 days
Oslo University Hospital	165	12
Sapienza Universita di Roma	91	7
Aneurin Bevan University Health Board	86	12
Leicester Royal Infirmary	75	9
University Hospitals Birmingham	67	2
Università degli Studi di Sassari	63	2
The Royal London Hospital	62	3
Arcispedale Sant'Anna	58	12
Heart of England	57	3
Antrim Area Hospital	55	4
York Hospital	54	2
Bradford Teaching Hospitals	41	1
The Christie	38	2
Royal Alexandra Hospital	36	4
The Royal Marsden	35	4
Ospedale San Paolo - Polo universistario	33	4
Royal Blackburn Hospital	29	3
Royal Surrey County Hospital	26	0
Fondazione IRCCS Policlinico San matteo	25	5
A.O.U Policlinico "P. Giaccone" - Palermo	23	1
Musgrove Park Hospital	23	2
Haukeland University Hospital	19	0
Karolinska University Hospital	19	11
King's College Hospital	18	3
Clty Hospitals Sunderland	17	3
St George's Hospital	17	0
The Freeman Hospital	17	2
University Hospitals of Morecambe Bay	13	2
Queen Elizabeth Hospital, King's Lynn	12	1
Stavanger University Hospital	10	0
Medway Maritime Hospital	9	2
Modena	8	3
St Mary's Hospital - Imperial College	8	1
Central Manchester	7	1
Hospital Universitario Rio Hortega	7	2
Linköping University Hospital	7	3
Queen Alexandra Hospital	7	1
North Middlesex	6	0
Shrewsbury and Telford Hospitals	6	1
James Cook University Hospital	5	0

Data completeness

Site Name	Primary outcome complete (%)
City Hospitals Sunderland	100
GB Morgagni-L Pierantoni Hospital, Forli	100
Haukeland University Hospital	100
King's College Hospital	100
Medway Maritime Hospital	100
North Middlesex	100
Queen Elizabeth Hospital, King's Lynn	100
Royal Bournemouth Hospital	100
Royal Preston Hospital	100
Royal Surrey County Hospital	100
Shrewsbury and Telford hospitals	100
St Mary's Hospital - Imperial College	100
Stavanger University Hospital	100
The Freeman Hospital	100
York Hospital	100
The Royal London Hospital	98.2
Arcispedale Sant'Anna	97.5
Leicester Royal Infirmary	95.3
St George's Hospital	94.1
University Hospitals of Morecambe Bay	90.9
Royal Alexandra Hospital	90
University Hospitals Birmingham	89.2
Heart of England	88.7
Royal Blackburn Hospital	84.6
The Royal Marsden	83.3
The Christie	82.9
Musgrove Park Hospital	81
Aneurin Bevan University Health Board	80.6
Bradford Teaching Hospitals	80
James Cook University Hospital	80
Ospedale San Paolo - Polo univeristario	78.6
Antrim Area Hospital	76.5
Oslo University Hospital - Rikshospitalet	75
Sapienza Universita di Roma	73.8
Fondazione IRCCS Policlinico San matteo	70
Università degli Studi di Sassari	68.3
Modena	66.7
Yeovil District Hospital	66.7
A.O.U Policlinico "P. Giaccone" - Palermo	65
The Royal Devon and Exeter Hospital	50
Queen Alexandra Hospital	33.3
Central Manchester	0
Hospital Universitario Rio Hortega	0
Karolinska University Hospital	0
Linköping University Hospital	0
Stepping Hill Hospital	0

Compliance

Site	CPAP compliance (%)
Antrim Area Hospital	100
Clty Hospitals Sunderland	100
Fondazione IRCCS Policlinico San matteo	100
GB Morgagni-L Pierantoni Hospital, Forlì	100
Linköping University Hospital	100
Medway Maritime Hospital	100
North Middlesex	100
Queen Elizabeth Hospital, King's Lynn	100
Royal Alexandra Hospital	100
Royal Preston Hospital	100
Shrewsbury and Telford hospitals	100
Stepping Hill Hospital	100
The Freeman Hospital	100
The Royal Devon and Exeter Hospital	100
University Hospitals of Morecambe Bay	100
Università degli Studi di Sassari	100
Yeovil District Hospital	100
The Royal London Hospital	96.7
Bradford Teaching Hospitals	94.4
King's College Hospital	90.9
Haukeland University Hospital	90
St George's Hospital	90
Oslo University Hospital - Rikshospitalet	89.8
Arcispedale Sant'Anna	88.9
Karolinska University Hospital	85.7
Sapienza Università di Roma	85.7
Stavanger University Hospital	85.7
Heart of England	83.3
St Mary's Hospital - Imperial College	83.3
York Hospital	81.8
Aneurin Bevan University Health Board	81.3
Musgrove Park Hospital	80
Royal Blackburn Hospital	80
Ospedale San Paolo - Polo univeristario	78.6
The Royal Marsden	77.8
Royal Surrey County Hospital	76.9
A.O.U Policlinico "P. Giaccone" - Palermo	75
The Christie	75
University Hospitals Birmingham	70.3
Leicester Royal Infirmary	68.2
Queen Alexandra Hospital	66.7
Modena	60