



# PRISM

# Newsletter

## ISSUE 4, FEBRUARY 2017

We are excited to announce that we have recently recruited over **1000** patients to the trial! Congratulations to York hospital who randomized the 1000<sup>th</sup> patient. We are lucky to have such a great group of investigators; it's a pleasure to work with all of you. Thank you to you for your continued hard work on the trial! We would also like to welcome a number of new sites who have opened since the last Newsletter:

- Royal Devon and Exeter Hospital
- Linköping University Hospital
- Royal Bournemouth Hospital
- Nevill Hall Hospital
- Stepping Hill Hospital
- Shrewsbury and Telford hospitals
- Karolinska University Hospital
- St Mary's Hospital
- Central Manchester Hospital
- Northampton General Hospital



We are looking forward to opening PRISM sites in Spain, Sweden and South Africa in the very near future.



### ***Making PRISM a success***

We are now recruiting over 150 patients per month, which is an absolutely fantastic achievement: we very proud of the job you are all doing! Since PRISM is a clinical trial, success is not only about randomising lots of patients. In order to see if CPAP has positive effect on patients, we need very high compliance with the intervention and outcome assessments on all patients. Without this, all of our hard work is in danger of being overlooked if CPAP compliance is low or there are missing data.

### ***What does success look like at my hospital?***

- Every patient that is randomised into the CPAP group receives CPAP
- Every patient that is randomised has a primary outcome assessment
- Data from the paper CRF is entered on to the web database as you go along

## *Tips for maximising success*

- Randomise patients as late as possible into the procedure or afterwards to ensure that the patient is still eligible for the trial and can successfully receive CPAP.
- Where a member of the clinical team is responsible for delivering CPAP it is often helpful if a research nurse is present to ensure CPAP is started in a timely way.
- During consent show the patient the CPAP mask or hood while discussing the treatment in more detail. This will help reduce the number of patients turning down the intervention.
- Sometimes the patient might find CPAP uncomfortable and ask for it to be removed. It is perfectly fine to have short breaks during CPAP but we would encourage you to offer it again after a short break. Aim for a total duration of 4 hours.

### Problem getting notes?

A large number of trial sites find it difficult to access medical notes after patients have been discharged. To avoid difficulties and to reduce missing data, we recommend reviewing the medical notes before the patient is discharged, where possible.

## *30 day follow up*

As a part of the follow up procedures we would like you to contact the patient 30 days after randomisation. If the patient is contacted after the nominated date, the follow up should only include data from the first 30 days. It is often helpful to try to contact the patient at different times of the day including weekends. In most cases the follow ups are based on the patient's medical records and the information obtained during the phone call. On those rare occasions when the patient is unreachable, please contact the GP about illnesses between hospital discharge and 30 days. In these cases you would not be able to complete the EQ5D.



CPAP training in full swing in the Royal London Hospital under the watchful eye of Tim Martin, our lead research nurse for PRISM.

## Recruitment

| Site Name                               | Total |
|---|-------|
| Oslo University Hospital                | 141   |
| Sapienza Università di Roma             | 69    |
| Aneurion Bevan Health Board             | 62    |
| Leicester Royal Infirmary               | 59    |
| Heart of England Hospital               | 50    |
| The Royal London Hospital               | 50    |
| University Hospitals Birmingham         | 50    |
| Università degli Studi di Sassari       | 47    |
| York Hospital                           | 47    |
| Antrim Area Hospital                    | 44    |
| Bradford Teaching Hospitals             | 38    |
| Arcispedale Sant'Anna                   | 30    |
| The Christie Hospital                   | 28    |
| The Royal Marsden Hospital              | 27    |
| The Royal Alexandra Hospital            | 26    |
| The Royal Surrey County Hospital        | 24    |
| The Royal Blackburn Hospital            | 23    |
| Ospedale San Paolo - Polo Univeristario | 23    |
| Musgrove Park Hospital                  | 20    |
| St George's University Hospital         | 17    |
| A.O.U. Policlinico "P. Giaccone"        | 16    |
| Sunderland Royal Hospital               | 13    |
| Fondazione IRCCS Policlinico San Matteo | 13    |
| The Freeman Hospital                    | 13    |
| Haukeland University Hospital           | 11    |
| Queen Elizabeth Hospital                | 10    |
| Stavanger University Hospital           | 10    |
| King's College Hospital                 | 9     |
| Furness General Hospital                | 8     |
| James Cook University Hospital          | 5     |
| Medway Maritime Hospital                | 5     |
| North Middlesex Hospital                | 4     |
| Furness General Hospital                | 3     |
| Queen Alexandra Hospital                | 3     |
| Shrewsbury and Telford Hospitals        | 3     |
| St Mary's Hospital                      | 3     |
| Central Manchester Hospitals            | 2     |
| The Royal Bournemouth Hospital          | 1     |
| The Royal Preston Hospital              | 1     |
| The Royal Devon and Exeter Hospital     | 1     |
| Yeovil District Hospital                | 1     |

**Compliance**

| <b>Site</b>   | <b>CPAP compliance (%)</b> |
|---|----------------------------|
| Antrim Area Hospital                                | 100                        |
| City Hospitals Sunderland                           | 100                        |
| Fondazione IRCCS Policlinico San matteo, Pavia      | 100                        |
| Haukeland University Hospital                       | 100                        |
| North Middlesex                                     | 100                        |
| Queen Elizabeth Hospital, King's Lynn               | 100                        |
| The Royal Alexandra Hospital                        | 100                        |
| Shrewsbury and Telford hospitals NHS trust          | 100                        |
| Stavanger University Hospital                       | 100                        |
| The Freeman Hospital                                | 100                        |
| University Hospitals of Morecambe Bay               | 100                        |
| Università degli Studi di Sassari                   | 100                        |
| The Royal London Hospital                           | 95.8                       |
| Bradford Teaching Hospitals                         | 94.1                       |
| Arcispedale Sant'Anna University Hospital - Ferrara | 93.8                       |
| Oslo University Hospital - Rikshospitalet           | 89.3                       |
| Sapienza Università di Roma                         | 88.9                       |
| St George's Hospital                                | 88.9                       |
| Aneurin Bevan University Health Board               | 85.7                       |
| The Royal Blackburn Hospital                        | 85.7                       |
| King's College Hospital                             | 83.3                       |
| York Hospital                                       | 82.4                       |
| Heart of England Hospital                           | 81.8                       |
| The Royal Marsden Hospital                          | 80                         |
| Musgrove Park Hospital                              | 75                         |
| The Royal Surrey County Hospital                    | 75                         |
| Università degli Studi di Milano                    | 75                         |
| The Christie NHS Hospital                           | 73.3                       |
| University Hospitals Birmingham                     | 67.9                       |
| Leicester Royal Infirmary                           | 55.6                       |
| James Cook University Hospital                      | 40                         |



## Data completeness

| Site Name                               | Primary outcome complete (%) |
|---|------------------------------|
| Arcispedale Sant'Anna                   | 100                          |
| Fondazione IRCCS Policlinico San Matteo | 100                          |
| King's College Hospital                 | 100                          |
| Queen Elizabeth Hospital                | 100                          |
| The Royal Preston Hospital              | 100                          |
| The Royal Surrey County Hospital        | 100                          |
| The Royal London Hospital               | 100                          |
| York Hospital                           | 100                          |
| The Freeman Hospital                    | 100                          |
| Furness General Hospital                | 100                          |
| The Royal Alexandra Hospital            | 100                          |
| North Middlesex Hospital                | 100                          |
| Queen Alexandra Hospital                | 100                          |
| The Christie Hospital                   | 94.1                         |
| Ospedale San Paolo-Polo Univeristario   | 92.9                         |
| Antrim Area Hospital                    | 91.4                         |
| City Hospitals Sunderland               | 90                           |
| Heart of England Hospitals              | 87.5                         |
| University Hospitals Birmingham         | 86                           |
| Bradford Teaching Hospitals             | 85.3                         |
| The Royal Blackburn Hospital            | 83.3                         |
| Musgrove Park Hospital                  | 81.3                         |
| Università degli Studi di Sassari       | 80.6                         |
| Haukeland University Hospital           | 80                           |
| Oslo University Hospital                | 75.8                         |
| Stavanger University Hospital           | 75                           |
| Aneurin Bevan University Health Board   | 73.6                         |
| Sapienza Università di Roma             | 67.2                         |
| Leicester Royal Infirmary               | 65.4                         |
| The Royal Marsden Hospital              | 62.5                         |
| James Cook University Hospital          | 60                           |
| St George's University Hospital         | 50                           |
| A.O.U. Policlinico "P. Giaccone"        | 0                            |