

Since opening in February 2016 PRISM is now recruiting in 21 centres with 350 patients recruited. This is fantastic progress and we would like to thank you all for your efforts with the trial. We would like to welcome the following sites, who have opened since the last newsletter in July:

- James Cook University Hospital
- The Freeman Hospital
- Musgrove Park Hospital
- Royal Alexandra Hospital
- Sunderland Royal Hospital
- North Middlesex University Hospital

### ***Patient Recruitment***

Recruitment is proceeding very well for this stage of the trial – we are currently recruiting at a rate of 70-80 participants per month. In order to reach our recruitment target within the planned timescale we need to increase recruitment to 150 participants per month. This will mainly be achieved by opening new centres. We thank you all for working towards target recruitment of one participant per week.

<b>Site Name</b>	<b>Total</b>	<b>In Past 30 Days</b>	<b>Data Complete (%)</b>
Oslo University Hospital	68	19	70.5
Sapienza Universita di Roma	37	1	80.6
The Royal London Hospital	34	3	88.9
Leicester Royal Infirmary	29	10	5.9
York Hospital	25	7	100
Heart of England	25	2	95
Royal Gwent Hospital	24	8	0
Bradford Teaching Hospitals	23	2	30
Università degli Studi di Sassari	18	4	100
University Hospitals Birmingham	15	3	20
Royal Surrey County Hospital	14	2	91.7
Antrim Area Hospital	13	5	0
The Royal Marsden	10	4	0
Royal Blackburn Hospital	7	0	28.6
The Christie	6	1	75
St George's University Hospital	4	4	n/a
Royal Alexandra Hospital	3	3	n/a
Haukeland University Hospital	3	0	0
Musgrove Park Hospital	2	2	n/a
Stavanger University Hospital	2	2	n/a
Sunderland Royal Hospital	2	2	n/a
James Cook University Hospital	1	1	n/a
The Freeman Hospital	1	1	n/a
North Middlesex Hospital	0	0	0

## ***Data Completeness***

The table above includes a column for data completeness 40 days after randomisation. We very much appreciate everyone's efforts collecting and entering data on to the online database. Where possible we encourage data to be entered onto the database at the time of the 30-day follow up contact. We are keen to ensure that the trial data is as accurate as possible, which is facilitated by timely data entry.



*You can find the outstanding data for your site enlisted in "Incomplete CRFs from your site" under Worklists"*

## ***Protocol Deviations***

We appreciate that delivering the intervention can, at times, be challenging. Thank you for your perseverance when the CPAP is not straightforward. In the small number of cases where patients in the intervention group don't receive CPAP or they receive less than the required duration (or with significant interruption) it is important to complete a protocol deviation form. Where the reason for the protocol deviation meets an adverse event criterion, an adverse event form should also be submitted. These data will help us to understand why it is not possible to deliver CPAP in all circumstances.

## ***Inclusion Criteria***

What counts as "open surgery"?

The definition of open surgery for the trial is an incision larger than that required to remove the surgical specimen. So surgery that is predominantly laparoscopic but where a port site is extended to, for example, remove a specimen, mobilise a loop of bowel, do an anastomosis, will almost always be eligible. In general, at most centres oesophagectomies, gastrectomies, AAA repairs, extensive gynaecological procedures (E.g. TAH with major clearances) and major colorectal procedures (E.g. anterior resections) will be eligible. However, more minor abdominal procedures for example laparoscopies, laparoscopic cholecystectomies and, in most centres, right hemicolectomies using a predominantly laparoscopic technique, won't be suitable. We are aware that there is between-centre and between-surgeon variation in surgical technique, so it is best to discuss the procedures you intend to include with your surgeons to ensure that they meet the inclusion criteria. If you would like to discuss this further, please don't hesitate to get in touch.

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