Standard operating procedure

Monitoring Plan

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1. Purpose

This document will explain the process by which PRISM trial data entry will be monitored for completeness and quality, and establish guidelines for conducting monitoring visits and related tasks.

2. Visit scheduling

2.1 PRISM trial management group members will perform the monitoring visits.

2.2 The monitor will work with the site Principal Investigator (PI) and site staff to schedule monitoring visits.

2.3 Prior to the visit, the PI and site staff will receive a visit confirmation email and a list of trial participants (patients) for whom case note review and source data verification will be performed. The monitor will ensure that this information is communicated to the site personnel within a reasonable timeframe to allow sufficient time for record requests.

2.4 Monitoring visits will take place at each PRISM trial site as follows:

2.4.1 A Site Initiation Visit (SIV) will take place for each site. This may be conducted at the coordinating institution as a joint session, provided that at a minimum, the Principal Investigator and core research team for each site attend.

2.4.2 An initial visit will be organised following recruitment of 10 patients or at one year, whichever takes place first, at which source data verification (SDV) will be completed for a random selection of up to 10 patients – only less than 10 if less are recruited. If fewer than 10 patients have been recruited by one year, a meeting will be organised during the 1 year visit to discuss any issues.

2.4.3 A closeout visit will be organised at the end of the trial, at which SDV up to 30 day follow-up will be completed for a random selection of up to 10 patients recruited throughout the course of the trial. These patients must not have been reviewed previously. At this visit, the monitor will also complete SDV for 1 year data for the patients monitored at the initial visit.

2.4.4 If appropriate, additional monitoring visits may be organised to address specific trial related problems at a site. This will allow the monitor to review data entry at a site outside of the above timelines.

2.5 The PI and research staff will be expected to secure workspace for the monitor, and site staff should be available during the visits to facilitate monitoring activities.

2.6 The monitor will be available at the end of the visit to discuss any findings from the visit and answer any questions site staff may have. The Site PI (or nominated deputy) is expected to be available for a wrap-up meeting at the conclusion of the visit, as schedules allow.

3. Essential documents and Investigator Site File

3.1 The monitor will review the trial Investigator Site File to ensure essential documents are complete and current.

3.2 The monitor will ensure that the Delegation of Responsibilities Log is complete and signed.

4. Source Data Verification (SDV)

4.1 The purpose of monitoring data entry for the PRISM trial is to ensure that the data returned via the online database is complete and accurate.

4.2 SDV, comparing patient medical notes against both the PRISM paper CRF and online database, will be used to perform checks. 100% SDV will be carried out for a maximum of 10 selected patients at each visit.

4.3 The following sections of the CRF will be verified:

Section 1: Inclusion, Exclusion & Randomisation Information
Section 2: Before Surgery
Section 3: During Surgery
Section 4: Trial Intervention Period
Section 5: 30 Day Follow-up

And if applicable:
Supplementary form: Discontinuation
Supplementary form: Adverse Event During CPAP

4.4 Section 6: One Year Follow-up will be verified at the closeout visit for each site for the patients monitored during the initial visit

5. Monitoring report and actions

5.1 A short, informal monitoring report will be produced after each visit. The report will outline any inaccuracies and incomplete data identified during the visit. This report will be sent to the PI who will be asked to:

1. Correct any outstanding errors and enter any missing data
2. Re-train staff in data entry for PRISM where necessary

5.2 The findings will also be reported to PRISM TMG.

5.3 The findings may require clarification, edits or amendments to be made to the PRISM training manuals/database, as well as perform wider systematic data cleaning. Such decisions will be at the discretion of the PRISM TMG.

6. Site self-assessment

6.1 Sites will be asked to review data entry for a random selection of 20% of each of their participants up to and including 30 day follow-up. Duplicate entry of data for these participants will be requested three months following completion of 30 day follow-up. SDV as described above will be carried out regardless of whether a patient is automatically selected for duplicate data entry.