Plan Overview

A Data Management Plan created using DMPonline

Title: Comparing the effectiveness of side-lying sleep positioning to back-lying at reducing oxygen desaturation resulting from Sleep Disordered Breathing in infants with cleft palate

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Project abstract:

Why is sleep important in cleft palate? The craniofacial abnormalities found in infants and children with cleft palate (CP) lead to increased risk of sleep disordered breathing (SDB) and obstructive sleep apnoea (OSA). In children and adults sleep position is known to influence the patency of the airway during sleep. Altering sleep position in infants with CP may offer a ‘low-cost, high impact’ intervention to limit the negative impacts of SDB on child development. What are the consequences of SDB in infants with CP? Children with CP are at increased background risk of impairment in ‘learning, memory and cognition’, with SDB representing an additional risk to cognitive development. Infants with CP are also at risk of poor weight gain and ‘failure to thrive’, which can be further exacerbated by co-existing SDB. The increased work of breathing associated with SDB, leads to increased energy expenditure, in infants already at risk of reduced calorific intake due to cleft-related feeding difficulties. Poor nutritional status is a significant, and potentially reversible, barrier to the desired repair of a CP in infancy and early childhood. Our feasibility study (PB-PG-0213-30058). The design and conduct of the proposed randomised controlled trial will benefit from lessons learned from both our feasibility and our other previous studies. We demonstrated existing significant variability in advice given about sleep position with some centres recommending back-lying and others side-lying. Sample size calculations were based on this multi-source data. Parents in our feasibility study knew that sleep position advice for infants with CP changes regularly. They understood why not adhering to 'national guidance' (DoH 2009, Back to Sleep campaign) could be necessary as their infants are “different to normal infants”. How will this study benefit infants with cleft palate and their parents? The proposed study will eliminate the current uncertainty and variability in advice provided to parents of infants with CP, whilst potentially limiting the negative impact of SDB on development. This work has been prioritised and received unanimous support from Cleft, Lip & Palate Association (CLAPA), CFSGBI and Clinical Nurse Specialists. Aim. To determine the clinical effectiveness in infants with CP of side-lying as compared to back-lying sleep positioning in reducing oxygen desaturation resulting from SDB. Inclusion criteria. Infants diagnosed with an isolated CP under the care of a collaborating centre, who are 3 to 5 weeks of age when monitored. Exclusion criteria. Infants with associated cleft lip, born prematurely, with cardiorespiratory disease and those requiring an intervention to assist with breathing or feeding. Primary

outcome: Oxygen saturation during sleep expressed as 4% oxygen desaturation index (ODI-4) will be measured using pulse oximetry. Research Plan: Internal pilot qualitative research study to support parents and clinicians regarding randomisation, seeking to identify and address early any barriers to recruitment. Multicentre randomised controlled trial of side-lying compared with back-lying sleep positioning in reducing oxygen desaturation resulting from SDB in infants with CP at one month of age. Co-development of new UK recommendations with parents and the Cleft Lip & Palate Association (CLAPA) regarding sleep position for infants with cleft palate.

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Copyright information:

Comparing the effectiveness of side-lying sleep positioning to back-lying at reducing oxygen desaturation resulting from Sleep Disordered Breathing in infants with cleft palate

Data Collection

What data will you collect or create?

-Primary outcome:

Oxygen saturation during sleep at 1 month of age (expressed as 3% and 4% oxygen desaturation index (ODI-3 and -4).

-Secondary outcomes:

i. Sleep questionnaire – Extended Brief Infant Sleep Questionnaire (extended BISQ),

ii. Other commonly used oximetry parameters including mean SpO2, nadir SpO2, the proportion of total sleep time (TST) with oxygen saturation below 97% , 95%, 90% and 80%, and apnoea hypopnoea index (AHI) at age 1 month.

iii. Weight and height at age 1 month

iv. Adverse events.

How will the data be collected or created?

-Primary outcome:

data collected by oximetry machine Masimo Rad-8. Measurement done by parents at home.

-Secondary outcomes:

i. Sleep questionnaire – Extended Brief Infant Sleep Questionnaire (extended BISQ) completed by parents

ii. oximetry machine Masimo Rad-8 - Measurement done by parents at home.

iii. data collected by reseacrh nurse, recorded in the CRF

iv. parental or nurse reported, recorded in the CRF

Documentation and Metadata

What documentation and metadata will accompany the data?

data (demographic data, weight, height, Adverse events) will be collected in a bespoke CRF and transcribed into study-specific database.

Oximetry machine will save its results in a form of a data file which will be dowloaded onto a study-specific database.

BISQ will be provided to parents as a paper copy and results to be transcribed into a study-specific database.

Ethics and Legal Compliance

How will you manage any ethical issues?

Participants in the SLUMBRS2 will be NHS patients and the study will be subject to a full NHS ethics procedure. Appropriate approvals will be sought via Integrated Research Application System. All team members will follow Good Clinical Practice guidelines. Fully informed consent will be obtained from participants by a specialist cleft nurse from participants' respective centres. There will be a full patient information sheet on NRES template.

Ethical issues in relation to the study were considered and addressed following the SLUMBRS feasibility study. For SLUMBRS2 we have expanded the education component available to parents (creation of an instruction video), changed the machines used for assessments (smaller and less complicated) and reduced intervention to a single measurement timepoint.

The sponsor has well-established standard operating procedures for secure and confidential data handling and sharing, and will take measures to ensure we are compliant with the General Data Protection Regulation (2018).

All participating sites will achieve ethical and HRA approval prior to the start of the funded project.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

No IP will be produced or improved during the proposed research.

Storage and Backup

How will the data be stored and backed up during the research?

Study data will be stored in Cardiff CTU purpose-build database. Cardiff CTU will manage security and backup.

How will you manage access and security?

Access to data will be managed by Cardiff CTU. Access will be granted only to the study team and will be protected with the password and role-specific approvals will be granted in relation to the database.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

data will be archived as per sponsor's SOP. Otherwise data will be published and available in its anonymised form.

What is the long-term preservation plan for the dataset?

Study will be archived as per sponsor's (MFT) SOP for the period of 15 years.

Data Sharing

How will you share the data?

data will only be accessed by the study team. sponsor will have access to data if required for monitoring purposes. Regulatory authorities will have access to data if required.
Oximetry recording may be shared with the clinical staff (with parents permission) if a research reading is deemed to be abnormal by the study team.

Are any restrictions on data sharing required?

no, as only allowed in defined circumstances.

Responsibilities and Resources

Who will be responsible for data management?

overall responsibility for the data management is taken by the study Chief Investigator Prof Iain Bruce.

What resources will you require to deliver your plan?

This study will be sponsored by the Manchester University NHS Foundation Trust and subject to normal governance arrangements. Overall responsibility for project management will be assumed by the Chief Investigator (Bruce). Day-to-day operational management will be overseen by the Study Management Group (SMG), chaired by the CI and comprised of members of the investigative team. Regular SMG meetings will be held every three months to discuss progress and obstacles to

progression; with minutes taken from all meetings. The CI and members of the investigative team have considerable experience of successfully collaborating on the SLUMBRS feasibility study and a track record of effective team-work, communication and problem-solving. There will be an independent data monitoring committee (DMC). Data security will be maintained using a secure web-based data entry procedure and local secure site-specific data storage procedures. Data management and governance will use standard sponsor procedures and material will be kept for 15 years as per sponsor SOPs.

Day-to-day coordination and management of the project will be conducted from the MFT by the Senior Trial Coordinator (Metryka, extensive experience gained during preparation of SLUMBRS feasibility manuscript, SLUMBRS II funding application and other of the CI's research projects), a Trial Manager (Cardiff CTU providing consultation and oversight) under the supervision of CI. This team will coordinate the research sites, facilitate effective management of, and communication between, the various trial components, to monitor progress and to ensure targets and deadlines are kept. They will report to the investigative team and the SMG and will oversee governance arrangements, registration and formal reporting, budget and timeline monitoring, trial, protocol and procedures, randomisations and coordination of training, recruitment, and outcome evaluation. They will liaise closely with the CTU to establish and maintain data management and quality assurance procedures.

Statistician Prof Tanya Walsh was involved in the design and methodology of the trial proposal from the beginning (feasibility study). She will assist the Cardiff CTU with oversight of an independent randomisation facility and an online data entry service. MFT quality department together with the trial coordinator will supervise the ongoing data entry and management. Data analysis in the project will be conducted by MFT statistics department under the guidance and supervision of Prof Walsh.