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Comparing the effectiveness of side-lying sleep positioning to back-lying at reducing oxygen desaturation resulting from Obstructive Sleep Apnoea in infants with cleft palate (SLUMBRS2).

Parent/Guardian Information Sheet (Version 1.1, 25 Nov 2020)

We would like to invite you and your baby to take part in our research study. Joining the study is entirely up to you, so before you decide we would like you to understand why the research is being done and what it would involve for your child and you. One of our team will go through the information sheet with you and answer any questions you have. Please take time to read the information and feel free to talk to others about the study if you wish.

Important things you need to know

- We want to find the best way to answer the question, "what is the best sleeping position for a baby with isolated cleft palate?"
- SLUMBRS2 study will answer this question by comparing the levels of oxygen in the bloodstream of babies whilst sleeping on their side or on their back.
- Taking part will involve monitoring your baby sleeping at home, using a sensor attached to their foot that records changes in the amount of oxygen levels in the blood. This will not involve any discomfort for your baby.
- Sleep monitoring will take place at night.
- We will be randomly assigning babies to one of two sleeping positions: side or back lying. We will ask you to follow the assigned sleeping position only during the monitored sleep.

Why are we doing this research?

Currently, doctors and nurses working within your cleft team do not know the best advice to give parents about the safest sleep position for a baby with a cleft palate. Although some UK cleft centres advise that babies should sleep on their backs other centres advise positioning the baby on their side as their experience has been that the child breathes easier during sleep in this position. However, we still do not know which sleeping position is best.

If a baby's airway becomes regularly narrowed during sleep then the levels of oxygen in the blood stream will drop and the levels of the waste gas carbon dioxide will increase, which can affect health in severe cases. Children with cleft palate can be at increased risk of this airway narrowing which has led doctors and nurses to think about what is the best sleeping position for children with a cleft palate.

We want to find out the answer the question, "what is the best sleeping position for a baby with isolated cleft palate?"

We have asked all Cleft Centres in the United Kingdom to be involved in the study. Each of the centres will invite parents and their babies to take part in the study.

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Why have we been asked to take part?
You and your baby have been invited to take part because you are a parent of a baby who has an isolated cleft palate and your cleft network is participating in the study. We would like to recruit 244 babies and their families.

What would taking part involve?
We would like to look at the effect of sleeping position on oxygen level in the blood.

This will involve monitoring your baby sleeping at home, using a sensor attached to their foot that records changes in the amount of oxygen in the blood. This will not involve any discomfort for your baby.

We would like to monitor your baby for a period of 1 night's sleep, hopefully lasting 5 hours or more, when they are about 1 month old. We will also ask you to complete a form about your baby's sleep. Participants recruited in the first 6 months from the start of the study will also be asked to complete a questionnaire about their experiences of participating in the study. Please check with your cleft nurse if this will be applicable to you.

We will randomly assign your child to one of the sleeping positions: side or back lying. You will only need to adhere to that advice during the 1 night of sleep when your child will be monitored. After your participation has finished you will follow the advice given by your cleft centre.

If you agree for your baby to take part, you will be asked to sign a consent form. Once you have consented to take part we will collect some information about you and your baby, this may be done at a routine clinic visit, during the first research home visit or telephone/ video call visit, whichever occurs first.

Day 1

- The research nurse will collect your baby's most recent weight, length and head circumference as recorded in the Red Book and ask you some questions about your baby's medical history.
- We will ask you to complete a short questionnaire about your baby's sleeping habits and a "sleep log" – which will collect information such as your baby's sleeping position and feeding times. This will be provided to you as a paper or electronic version, depending on your preference.
- Your cleft nurse will set up the sleep monitoring machine (oximeter) and show you how to switch the monitor on and off and also how to connect the sensors to your baby. This may be done during the home visit or via a video call.
- You will be given written instructions of how to use the monitor as well as information of where to find an instruction video, in case you need to refresh your knowledge.
- You will be asked to monitor your baby for a period of time (at night) while they are asleep. The nurse will not be there for the sleep monitoring *but you will be able to contact her / him if you have any concerns.*

What to do when the alarm goes off on the machine (oximeter)?

The alarm on the machine that measures oxygen levels in the bloodstream (oximeter) is a safety measure to alert if there is a prolonged fall in blood oxygen levels that could be a risk to your baby. Thankfully, life-threatening events are very rare, and in fact the alarms are usually switched off for home sleep studies in the UK. We have decided to have the alarms switched on for this research study. Both of the sleep positions being compared in our study are used as standard in different parts of the country.

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We know that all babies have brief falls in oxygen levels during sleep which may trigger the alarm. This is entirely normal and is due to normal variations in breathing patterns in babies. The alarm can also go off for other reasons such as the baby moving or the sensor becoming detached from the foot. It is very unlikely if the alarm goes off that your baby is in danger especially if the alarm is brief. We recommend that the baby's cot is placed in your bedroom for the night(s) of monitoring. If the alarm goes off and does not stop within a few seconds you should check that your baby is breathing (like you would do if you bought a home apnoea alarm) and make sure that your baby has not rolled over into a face down position.

We want to find out what is happening to the amount of oxygen in your baby's blood stream whilst they are asleep. To help us recognize when the oxygen recording from the machine is from sleep, we ask you to pull the cable out of the machine while keeping the sensor on your child's foot during feeds/nappy changes and complete the sleep log accordingly.

Do we have to take part?
It is up to you whether you and your baby take part in this study. Not taking part will have no effect on the care your baby receives now or in the future.
If you decide you do want to take part you will be asked to sign a consent form. This is to say that you understand what will happen. Even after signing the consent form, if you decide at any time that you and your baby no longer want to take part that is OK. You can withdraw from the study at any time without having to give a reason why.

What are the possible benefits of taking part?
This study will not help you or your baby directly. Instead it will help to answer the question of which sleep position is better for children with an isolated cleft palate. As part of this study you will find out your child's oxygenation levels during sleep. A Sleep Physiologist and Respiratory Paediatrician will review all collected data and will report all results to parents who are taking part in the study, via their local cleft team.

What are the possible disadvantage and risks of taking part?
You will be randomised to one of the two sleeping positions: side or back lying therefore for the night of the study you child may be asked to sleep in a position that is different to that advised by your centre. The equipment used to monitor the levels of oxygen is standard equipment that is routinely used, has no risk associated with it and is not uncomfortable for your baby.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the research nurse who will do their best to answer your questions [*local contact number*]. If you remain unhappy and wish to complain formally, you can do this by contacting your hospitals Patient Advice and Liaison Service (PALS). Details can be obtained from [*insert local details*]

Will our information be kept confidential?
Yes. All information collected about your child and you will be kept confidential and stored anonymously and securely under the provisions of the 2018 Data Protection Act.

Your name and your baby's name will be removed from all the information we collect and the information will be given a code so that you, and they, cannot be identified. The information with the code will be entered into the main computer (database) via a secure internet connection. The database is kept securely in the Centre for Trials Research at the University of Cardiff. Members of the research team entering the information will have a personal password to access the database.

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With your permission, your baby's GP, their health visitor and any other doctors involved in their clinical care will be told of their participation in the study. Your baby's relevant medical records may be inspected by the study team and regulatory authorities. This is to check that the study is being carried out correctly.

If you agree we would like to share with you relevant future research opportunities led by the Chief Investigator of SLUMBRS2, by the members of the SLUMBRS2 study management group or affiliated organisations: Cleft Lip and Palate Association (CLAPA) and the Cleft Collective.
Data collected for the purpose of this study will be stored for 10 years after the study finishes.

Impact of COVID-19 on the study.
Your local Cleft Centre will follow national and their local guidance with regards to Covid-19. All the equipment that you receive will have been cleaned as per the local policy. Sensors for the oximetry machine that you will receive are single use and will come to you in an unopened packaging. Any information that is gathered from you will be done in accordance with local practice, e.g. this may be via telephone or video call and not in person. If appropriate and agreed by you, study documents will be exchanged with you via email.

What will happen to the results of the study?
The results of the study (using only anonymous data) will be made available to the parents that took part in the study, parents and children affected by cleft via the Cleft Lip and Palate Association (CLAPA) website and through UK Cleft lip and palate centres. We will also publish a study summary on the following websites:
1. Healthtalk.org
2. Mft.nhs.uk
3. Cleft Palate Professional Organisations (http://craniofacialsociety.co.uk/)
4. https://www.lullabytrust.org.uk/

We have commissioned Healthtalk.org to produce an animated video summary of research to be shared on the websites mentioned.
The results will also be published in scientific journals and may be presented at conferences.

Who is organising and funding the study?
The organisation responsible the study is Manchester University Hospital NHS Foundation Trust. The study is funded by a "Research for Patient Benefit" grant from the National Institute of Health Research (NIHR). The NIHR is funded by the Department of Health and is part of the NHS.

How have patients and the public been involved in this study?
The Cleft Lip and Palate Association (CLAPA) were involved in the design of this study. We will have input from parent representatives, who are part of the Study Advisory Group, throughout the study. The Study Advisory Group provides independent advice to the SLUMBRS2 study team.

Who has reviewed this study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your / your baby's interests. This study has been reviewed and given favourable opinion by [*Insert name*] Research Ethics Committee.

If you decide you do not want to take part
We also understand that parents may have many different reasons for choosing not to consent and this is also important information for researchers. We would like to know (if you wish to tell us) your reasons for declining to be involved in the study. Knowing this will help

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us amend the study. Your decision will be respected and nobody will try to change your mind.

How will we use information about you?

Medical records of your baby will be accessed to obtain information for the research purposes. We will also need to use information from [you] for this research project.

This information will include:

- Your child's date of birth
- Your contact details including e-mail address
- Your home address for courier equipment pick up

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to slumbrs@mft.nhs.uk , or
- by ringing us on [insert number]

Thank you for reading this Parent/Guardian information sheet and considering yours and your baby's participation in this study.

If you'd like to find out more about the study please contact:

Name and Surname of the local PI [telephone] and [email]
Or please email the Study Manager slumbrs@mft.nhs.uk