Queensland Government

CHILDREN'S HEALTH QUEENSLAND

PARENT/GUARDIAN INFORMATION STATEMENT

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00007:658862

Title: **Bronchiolitis and Nasogastric (BANG) Feeding: A randomised control trial**

HREC Number: **HREC/15/QRCH/8**

Principal Investigator: **Dr Alyssa Courtney (via switch on 3068 1111 or alyssa.courtney@health.qld.gov.au)**

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to ask your child to participate in a research project that is explained below.

It is ok to say no

Introduction

We are asking for your child to take part in the above research project because they have bronchiolitis and may be commencing nasogastric feeds (feeds given via a soft plastic tube which is inserted down the nostril into the stomach) as part of their routine clinical care.

This Participant Information Sheet/ Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want your child to take part in the research. Please read this information carefully. Ask questions about anything that you don't understand or want to know more about.

Participation in this research study is voluntary. If you do not wish your child to take part, they do not have to. The child will receive the best possible care whether or not they take part.

You will be given a copy of this Participant Information and Consent Form to keep.

What is the purpose of this research?

Nasogastric feeds are part of standard routine clinical care for children with bronchiolitis. This research project is investigating which is the best method of administrating the nasogastric feeds, either continuously or given in bolus amounts 2-3 hourly. At Lady Cilento Children's Hospital, Brisbane it is common for infants with moderate to severe respiratory distress to be commenced on continuous nasogastric feeds. These feeds are then gradually upgraded to bolus feeds as the child's clinical condition improves. Following this, the child is then trialled on oral feeds. However, at other similar tertiary children's hospitals such as the Royal Children's Hospital, Melbourne and Princess Margaret Hospital in Perth, bolus feeding, rather than continuous feeding, is used.

There is no current evidence to support the benefits of continuous feeds over bolus feeds or vice versa. The process of upgrading from continuous to bolus to oral feeds can take 24 – 72 hours, potentially prolonging hospital admission and prolonging the impact on family life.

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What does participation in this research involve?

If you consent, your child will participate in a trial to determine which is the better feeding method. Sometimes, when we do not know which treatment is best for treating a condition we need to compare different treatments. To do this we put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

If you agree for your child to participate in this study, your child will be randomly allocated to receive either continuous nasogastric feeds or bolus nasogastric feeds. This means that if the child is assigned to receive bolus feeds he/she will be given a volume of feed every 2 - 3 hours. This mimics the usual feeding pattern of infants 0 -12 months. If the child is assigned to receive continuous feeds the feed will be trickled in continuously over a 24 hour period. The overall volume of feed will be the same and all feeds will be delivered via the feeding tube that has already been inserted into the baby's stomach through his/her nose. The feed that the baby receives will be his/her usual feed, whether that be expressed breast milk or formula. Your child's treatment and care, such as increasing or decreasing the amount of feeds and when your child can recommence oral feeding, will be exactly the same as someone who is not in the study. Your child will not require any other additional tests. The research team may call you once after discharge home to routinely check on your child's progress.

Other relevant information about the research project

Although this study is being conducted at Lady Cilento Children's Hospital, the results of the study will be applicable to children in other hospitals. We will be recruiting at least 200 children into this study and anticipate that the study will be completed by December 2019.

Does my child have to take part in this research project?

Participation in any research project is voluntary. If you do not wish for your child to take part, they do not have to. If you decide that they can take part and later change your mind, you are free to withdraw your child from the project at any stage. If you do decide that your child can take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision that your child can or cannot take part, or that they can take part and then be withdrawn, will not affect their routine treatment, relationship with those treating them, or their relationship with Children's Health Queensland.

What are the alternatives to participation?

If you do not consent for your child to participate in this study they will be given either continuous or bolus nasogastric feeds at the discretion of the admitting medical officer based on your child's clinical condition.

What are the possible benefits of taking part?

We cannot guarantee or promise that your child will receive any benefits from this research.

What are the possible risks and disadvantages of taking part?

As both continuous nasogastric feeds and bolus nasogastric feeds are widely used in hospitals similar to the Lady Cilento Children Hospital, we do not anticipate that there will be any increased risks for your child if they participate in this study.

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All children having nasogastric feeds, irrespective of if they are in a study or not, are monitored closely. Routinely, if a child develops worsening respiratory distress and cannot tolerate oral/ NG fluids, then intravenous fluids may be commenced and the child is made 'nil by mouth'.

What if I withdraw my child from this research project?

If you wish to withdraw your child from this study please advise the study team. You will be asked to complete and sign a "Withdrawal of Consent' form. This will be provided to you by the study team.

If you do withdraw your consent during the study, the information already collected in the study will be retained, to ensure the results of the study can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the study results. You will be unable to have your child's data already collected removed.

In addition, to ensure that the study results are complete, we would also like your permission to continue to collect data (e.g. total length of hospital stay) for your child. We will ask your permission to do this.

What will happen to information about my child?

All personal data collected during this research will be kept in a locked filing cabinet and only accessed by the research team. It is anticipated that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that your child cannot be identified (this is called non- identifiable data), except with your permission.

The information will be kept for a total of 7 years, after which it will be destroyed. Your child's information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. This complies with the recommended Australian guidelines for retention of research data.

What if something does go wrong?

In the unlikely event that your child does suffer any injuries or complications as a direct result of participating in this study, you should contact the study team as soon as possible, who will assist you in arranging appropriate medical treatment. Your child will receive all medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. You do not give up any legal rights to compensation by participating in this study.

Who has reviewed the research project?

This study has been approved by the Children's Health Queensland Hospital and Health Service Human Research Ethics Committee and authorised to be conducted at the Lady Cilento Children's Hospital. Should you wish to discuss the study with someone not directly involved, in particular, any matters concerning policies, information about the conduct of the study or your rights as a participant, or you wish to make a confidential complaint, at any time, you may contact the Co-ordinator of the Ethics Committee on 3069 7002 or email (CHQETHICS@health.qld.gov.au). If the phone is unattended, please leave a message and your call will be answered as soon as possible.

Who can I contact for more information?

If you want any further information concerning this project or have any questions during the study you can contact the principal study doctor (Dr Alyssa Courtney) via email (alysssa.courtney@health.qld.gov.au) or Lady Cilento Children's Hospital switch board on 3068 1111.

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CHILDREN'S HEALTH QUEENSLAND

PARENT/GUARDIAN CONSENT FORM

Title: **Bronchiolitis and Nasogastric (BANG) Feeding: A randomised control trial**

HREC Number: **HREC/15/QRCH/8**

Principal Investigator: **Dr Alyssa Courtney (via switch on 3068 1111 or alyssa.courtney@health.qld.gov.au)**

Declaration by Parent/Guardian

- I have read the Parent/Guardian Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to my child participating in this research project as described and understand that I am free to withdraw them at any time during the research project without affecting their future health care.
- I understand that the project is for the purpose of research and not for treatment, so may not directly benefit me or my child.
- I have been informed that the confidentiality of the information will be maintained and safeguarded and give permission for access to my infant's medical records for the purpose of research.
- I give permission for medical practitioners, other health professionals, and hospitals outside this hospital, to release information concerning my infant's disease and treatment which is needed for this trial and understand that such information will remain confidential.
- I understand that I will be given a signed copy of this document to keep.

Name of Child (please print)			
Name of Parent/Guardian (please print)			
Signature of Parent/Guardian		**Date**	

Declaration by Nurse or Medical Officer

I have given a verbal explanation of the research project, its procedures and risks and I believe that the parent/guardian has understood that explanation.

Name of Nurse or Medical Officer (please print)			
Signature		**Date**	

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CHILDREN'S HEALTH QUEENSLAND

PARENT/GUARDIAN REVOCATION OF CONSENT FORM

Title: **Bronchiolitis and Nasogastric (BANG) Feeding: A randomised control trial**

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Principal Investigator: **Dr Alyssa Courtney (via switch on 3068 1111 or alyssa.courtney@health.qld.gov.au)**

I hereby wish to **WITHDRAW** my intent for my child to participate further in the above research project and understand that such withdrawal will not jeopardise my child's future health care.

I understand that data collected up to the time I withdraw my child will form part of the study results and I will be unable to have my child's data already collected removed.

Child's Name (please print)	
Parent/Guradian Name (please print)	
Signature:	
Date:	**(DD/MM/YYYY)**

I give permission for the study team to continue to collect the primary outcome data for the purposes of this study.	
☐ **YES**	☐ **NO**

If a verbal withdrawal: In the event the parent / guardian decided to withdraw verbally, please give a description of the circumstances. Principal Investigator to provide further information here:

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_____

Principal Investigator's Name (please print)	
Signature:	
Date:	

Principal Investigator to sign the withdrawal of consent form on behalf of the parent / guardian if verbal withdrawal has been given.