COUNTIES MANUKAU DISTRICT HEALTH BOARD
A Community Partnership

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Parent/Whanau/Guardian Information Sheet

Randomised controlled trial of a combination of Dexamethasone and Adrenaline for Bronchiolitis (The DAB Trial)

A randomised controlled trial to see if Dexamethasone and Adrenaline improve outcome in the treatment of children with bronchiolitis.

Local Investigator:
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Introduction
We are inviting you and your child to take part in a research study looking at whether the use of Dexamethasone and Adrenaline makes a difference in the treatment of children with bronchiolitis. The study is taking place in 5 units in Australia and New Zealand.

Choosing to allow your child to take part in the study is voluntary (your choice). We realise that this is a very stressful time for you and thank you for taking the time to consider allowing your child to be part of our study.

Who is being asked to take part?
We are inviting all parents/whanau of children aged less than 18 months who are admitted to Starship Hospital PICU or Middlemore Hospital ICU with bronchiolitis to take part in the study.

What is the research study about?
Bronchiolitis is a common, acute, viral infection of the lower respiratory tract. It's mostly seen in children less than 1 year, but does affect children up to 2 years of age. Each year, an average of 73 children with severe bronchiolitis need admission to the intensive care unit. These children experience significant breathing difficulty and around 50% are ill enough to need help with breathing with a breathing machine called a mechanical ventilator.

The normal treatment for these children is to support their breathing, and to give them adequate feed and fluids while the virus runs its course. Dexamethasone and adrenaline nebules are medicines that we know from previous research reduce the number of children admitted to hospital after presenting to the emergency department with bronchiolitis. They are also already commonly used medications in other respiratory disorders of children such as croup and asthma. Dexamethasone is a corticosteroid that reduces swelling and inflammation and adrenaline enables inflamed airways that become narrow to re-expand. It is possible that these combined treatments may reduce the time in intensive care unit and the need for assistance with breathing. Some doctors use this medicine already because they believe it works. Others do not use this medicine because they do not believe it works or don't know whether it does.

What are the goals of this study?
The purpose of this research project is to see whether dexamethasone and adrenaline makes a difference in the treatment of children with bronchiolitis. We will compare a group of children who receive the standard treatment for bronchiolitis with a group of children who receive the standard treatment and dexamethasone and adrenaline. We will compare the chance of and duration of mechanical ventilation and the length of intensive care and hospital stay in both groups to see whether it improves the course of bronchiolitis. We aim to study a total of 274 children. We will also be conducting this research in other hospitals including Royal Childrens Hospital and Monash Medical Centre in Melbourne, and Princess Margaret Hospital for Children in Perth. The trial is aimed to run from 2012 to 2017

What does the study involve?
If you agree to have your child participate in the study, your child will receive the usual management we provide to every child admitted to intensive care with bronchiolitis. The only difference will be that your child will receive either dexamethasone and adrenaline nebulisations as well as standard care or standard care alone for the time that he or she requires intensive care.

Standard care includes the supportive treatment we would normally provide to all children with bronchiolitis.

After you have given signed consent, your child will enter into either the dexamethasone/adrenaline group or standard care alone group. The decision about which treatment your child receives is made by chance and each child has a 50/50 chance of receiving the dexamethasone/adrenaline or standard care alone. If entered into the dexamethasone/adrenaline arm dexamethasone will be given initially through a drip or less commonly an injection into the muscle followed by a repeat administration of a corticosteroid medication like dexamethasone (either methylpredinisolone or prednisolone) every 8 hours. The follow up doses will be either given in to a drip if one is present or else as a medicine orally. Adrenaline will be administered on 5 occasions through an oxygen mask and then again every 1 to 4 hours if required. Both medications will be given for up to 72 hours. There are no tests or observations required in addition to those that are ordinarily performed as part of routine standard care.

We will observe your child very carefully for the entire time they are in intensive care. When your child is well enough to leave intensive care this study will finish. There is no additional time required either in intensive care or in hospital as a result of the study. Your child's participation in the study is completed when they are well enough to leave the intensive care unit, and hence will be discharged from the research project. There is no need for any future follow-up.

Benefits for you and your child:
Dexamethasone and adrenaline are medicines already used for other respiratory disorders in childhood and are already occasionally used in bronchiolitis. In bronchiolitis these medications could reduce your child's need for respiratory support with mechanical ventilation and the duration of intensive care stay. Mechanical ventilation requires that a tube be placed in the opening of the airway and is then attached to a machine to assist with breathing. We cannot guarantee that improvement will occur. This is the reason for the study. However because we have used both of these medications for more than 20 years we do know that they are very safe.

Benefits for society:
The results of this study will indicate whether these medications are helpful in reducing the need for and duration of mechanical ventilation for children with bronchiolitis who are admitted to the intensive care unit

What are the possible risks, side-effects and/or discomforts?
All medications have associated risks of side effects. Adrenaline is a medication that also works on the heart to make it beat faster and harder when given in a vein through a drip. In this study adrenaline will be nebulised into the airway and lungs through the mouth and nose. Small amounts of adrenaline are absorbed into the blood stream and may increase the heart rate. When monitoring the heart rate we will not administer adrenaline if the resting heart rate is already very fast (higher than 180 beats per minute).

Dexamethasone/prednisone are corticosteroids that are commonly used in conditions such as croup (an infection of the upper airway) and asthma. They can cause some agitation but are usually well tolerated for a short period of time such as 3 days. Most of complications of corticosteroids are related to longer term use and do not occur with very short courses as will be used in this study.

What are the possible inconveniences?
Wearing a face mask for the administration of nebulised adrenaline will be required. A nebulisation often takes 3-5 minutes. The dose is likely to be repeated every 30 minutes for up to 5 hours and then between 1-4 hourly depending on the response for up to 3 days. The mask is removed after doses. Adrenaline and steroid medication can give a feeling of agitation but so to does respiratory distress from bronchiolitis.

Dexamethasone is administered by intravenous or intramuscular injection. Often an intravenous drip is already in place for the purpose of supportive care for bronchiolitis in the intensive care unit. No additional drips will be placed in this instance. The ongoing corticosteroid will be either given in a drip if it is present or else as a medicine orally. There will be no additional needle pricks as a result of the study.

Compensation
In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

General
If you require an interpreter one will be provided.

If you have any questions about the study please discuss these with the study co-ordinator. If you require more information about the study the study coordinator will provide this for you.

Information about each patient will only be accessed by those directly involved in the study. No data that could identify an individual patient will be accessible to anyone not directly involved in the study. No published data will identify any individual.

Your GP will be informed of your child's participation in this study when they receive the routine discharge letter which is written when your child leaves Intensive Care, and sent to the GP on discharge from Hospital.

Results of the study will be published in an appropriate journal at completion of the study. This will be several years away. If you wish to know the study outcome please inform the study coordinator.

If you are uncertain about the study then discussing it with your family/whanau may help. We are happy to talk to them about the study.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Free phone: 0800 555 050
Free fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz'

For Maaori Health Support, or to discuss any concerns or issues regarding this study, please contact: Maaori Health Support Te Kaahui Ora, Middlemore Hospital (09) 276 0044 ext 8138

This study has received ethical approval from the Northern X Region Ethics Committee.

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Consent Form

REQUEST FOR INTERPRETER

English	I wish to have an interpreter	Yes	No
Deaf	I wish to have a NZ sign language interpreter	Yes	No
Maaori	E hiahia ana ahau ki tetahi kaiwhaka Maaori/kaiwhaka pakeha korero	Ae	Kao
Cook Island Māori	Ka inangaro au i tetai tangata uri reo	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au	Io	Sega
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu	E	Nakai
Sāmoan	Ou te mana'o ia i ai se fa'amatala upu	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea	Io	Ikai

I have read and I understand the information sheet dated 24th May 2012 for volunteers taking part in the study designed to see whether Dexamethasone and Adrenaline make a difference in the treatment of children with bronchiolitis. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.

I understand that my child taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my child's care.

I understand that my child taking part in this study is confidential and that no material which could identify my child will be used in any reports on this study.
I understand that the treatment will be stopped if it should appear harmful to my child.

I understand the compensation provisions for this study.

I have had time to consider whether to take part.

I know who to contact if I have any questions about the medication or the study.

I wish to receive a copy of the results: YES/NO

I agree to my GP being informed of my child's participation in this study:
YES/No

I _____ (full name) hereby consent to my child taking part in this study.

Signed _____ Date _____

Project explained by _____

Project role _____

Signature _____ Date _____

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Other contact: ICU Research Nurses
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