Information statement and consent form

HREC Project Number: 32119

Research Project Title: Randomised controlled trial of a combination of Dexamethasone and Adrenaline for Bronchiolitis (DAB Trial)

Principal Researcher: Dr Ben Gelbart, Intensive Care Consultant

Paediatric Intensive Care Unit, Royal Children's Hospital

Version Number: 5 **Version Date:** 4/12/2012

Thank you for taking the time to read this **Parent/Guardian Information Statement and Consent Form**. We would like to invite your child to participate in a research project that is explained below. This document is 5 pages long. Please make sure you have all the pages.

If you speak a language other than English and would like this Information Statement and Consent Form in your language, please ask the person explaining this research project to you.

What is an Information Statement?
These pages tell you about the research project. It explains to you clearly and openly all the steps and procedures of the project. The information is to help you decide whether or not you would like your child to take part in the research. Please read this Information Statement carefully.

Before you decide if you want your child to take part or not, you can ask us any questions you have about the project. You may want to talk about the project with your family, friends or health care worker.

If you would like your child to take part in the research project, please sign the consent form at the end of this information statement. By signing the consent form you are telling us that you:

- understand what you have read
- had a chance to ask questions and received satisfactory answers
- consent to your child taking part in the project.

We will give you a copy of this information and consent form to keep.

1. What is the research project about?

Bronchiolitis is a common viral infection of the lungs. It is mostly seen in children less than 1 year old, but it does affect children up to 2 years of age. Each year an average of 100 children with severe bronchiolitis need to be admitted for treatment in the intensive care unit. These children experience significant breathing difficulty and many are ill enough to need a machine to help them to breathe. The standard treatment for these children is to support their breathing, and to give them adequate nutrition and fluids. There are no other medications that have been shown to benefit children with bronchiolitis.

Steroids and adrenaline are two medicines that are commonly used to treat children with severe croup or asthma, and recent research suggests that they may help children with mild bronchiolitis. Steroids are an anti-inflammatory medicine, and adrenaline helps to expand inflamed narrowed airways. It is possible that using a combination of these medicines may reduce the amount of respiratory support required for those children admitted to the intensive care unit with bronchiolitis. Some doctors already use this medicine in intensive care because they believe it works, but other doctors do not use this medicine because they do not think there is enough evidence that it works in intensive care patients.

The purpose of this research project is to see whether dexamethasone (a type of steroid) and adrenaline makes a difference in the treatment of children with bronchiolitis in intensive care. Adrenaline and dexamethasone are medicines that are approved for use in children by the Therapeutic Goods Administration, Australia.

We will compare a group of children who receive the standard treatment for bronchiolitis with a group of children who receive the standard treatment plus steroids and adrenaline. We will compare the amount of respiratory support needed, the duration of mechanical ventilation and the length of stay in intensive care and in hospital in both groups. We aim to study a total of 305 children from The Royal Children's Hospital, Melbourne. This research will also take place at Princess Margaret Hospital for Children in Perth and the Starship Hospital and Middlemore Hopsital in New Zealand.

2. Who is funding this research project?

This study has been initiated by the investigator Dr Ben Gelbart (an intensive care specialist at the Royal Children's Hospital). It is funded by the Paediatric Intensive Care Unit at The Royal Children's Hospital.

3. Why is my child being asked to be in this research project?

We are asking your child to take part in this study because he/she is less than 18 months old, has severe bronchiolitis and has been admitted to the Intensive Care Unit.

4. What does participation in this research involve?

Study length

The amount of time your child is in the study will depend on how long your child is in the intensive care unit. When your child is well enough to leave intensive care, their participation in this study will finish. Your child will not need to stay in intensive care or the hospital for any additional time due to their participation in this study.

Randomisation

As we are comparing two types of treatment, we will randomly assign (by chance, like flipping a coin) your child to one of the following groups:

- Standard treatment
- Standard treatment plus Steroid/Adrenaline

Study treatment

Your child will get the study treatment up to a maximum of 6 days. If your child is in the standard treatment plus steroid/adrenaline group he/she will get the following medicines:

- Dexamethasone at commencement of therapy followed by either methylprednisolone through a drip or prednisolone by mouth or a feeding tube given every 8 hours for the first three days, and then once a day for the next three days. The first dose of steroid (dexamethasone) will be given through a drip, but may also be injected into a muscle if a drip has not been inserted.
- Adrenaline will be given every 30 minutes for the first 2 ½ hours, and then every 1-4 hours for the

first 3 days, depending on your child's response to the treatment. It will be continued for a further three days if your child needs it. It will be given through an oxygen mask, so your child will breathe the medicine in. To breathe in the full dose of adrenaline takes 3-5 minutes.

Procedures

There are no extra tests or procedures required for this research. However, the following information that is collected as part of standard treatment, such as gender, weight, details of intensive care unit admission, type and level of breathing support will be used as part of this study.

5. What are my child's alternatives to taking part?

Participation in a research project is voluntary. Your child does not have to take part in this project if you do not want them to.

You and your child can change your mind and withdraw from the study at any time without giving a reason. Please tell us if your child plans to withdraw from the study so that we can let you know if there are any health risks or special requirements linked to withdrawing. If your child withdraws from the study we will use any information already collected unless you tell us not to.

Your decision will not affect any treatment or care your child gets, or your family's relationship with The Royal Children's Hospital.

Your child's alternatives to taking part in this study is:

- standard treatment for bronchiolitis including respiratory support and nutrition

6. What are the possible benefits for my child and other people in the future?

Steroids and adrenaline are already used for different breathing problems in children. If your child receives these medicines it is possible they could reduce your child's need for respiratory support with machines and the duration of their stay in intensive care. We cannot guarantee that improvement will occur. The results of this study will show if these medications are helpful in the treatment of children with severe bronchiolitis.

7. What are the possible risks, side-effects, discomforts and/or inconveniences?

Medical treatments often cause side effects. Your child may have none, some or all of the effects listed below. The effects may be mild, moderate or severe. We will closely watch your child for any side effects. Most side effects go away after treatment ends. If a side effect occurs we may need to stop your child's treatment. If this happens we will talk to you about this.

Adrenaline

Adrenaline works on the heart to make it beat faster, therefore your child's heart rate may be higher than usual. Blood pressure may also go up during adrenaline administration. Both of these parameters are closely monitored during your child's intensive care admission. Rarely, adrenaline may cause an abnormal heart rhythm. We will monitor your child's heart rate and rhythm, and if either becomes abnormal your child will be seen by a doctor and thought will be given as to whether it is safe or not to continue this therapy. Adrenaline is already commonly used in this fashion for other respiratory conditions in the intensive care and adverse events are rare. Adrenaline can cause a feeling of agitation and tremulousness. All these events resolve after discontinuation of adrenaline. Your child may need to wear an oxygen mask to receive adrenaline which may be uncomfortable. In the event that your child's heart is excessively high or heart rhythm changes adrenaline may be discontinued.

Dexamethasone

Dexamethasone is an anti-inflammatory medicine. When given to preterm babies in the first week of life there is some evidence that it affects brain development. However your child has a different condition, Dexamethasone and other agents like it have been and are commonly used in your child's age group for respiratory infections. Side effects from steroids are very uncommon when given for less than a week. Your child may have a feeling of agitation. The first dose of steroid medication will be given through a drip, if your child has one in place. No additional drip will be placed for the purpose of this research. If your child receives the steroid medication by needle, this may cause some discomfort for a short amount of time.

8. What will be done to make sure my child's information is confidential?

Any information we collect for this research project that can identify your child will be treated as confidential. We can disclose the information only with your permission, except as required by law.

All information will be stored securely in the Intensive Care Unit at The Royal Children's Hospital.

The following people may access information collected as part of this research project:

- the research team involved with this project
- The Royal Children's Hospital Human Research Ethics Committee

The information will be re-identifiable. This means that we will remove your child's name and give the information a special code number. Only the research team can match your child's name to their code number, if it is necessary to do so.

We will keep the information until the youngest participant turns 25 years old or for 15 years following the closure of the study – whichever date is latest. After this time, it will be destroyed.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access and correct the information we collect and store about your child. Please contact us if you would like to access this information.

When we write or talk about the results of this project, information will be provided in such a way that your child cannot be identified.

9. Will we be informed of the results when the research project is finished?

We will send you a summary of the overall results at the end of the study. The study is not due to end until 2017.

10. What happens if my child is injured during the project?

In the unlikely event that your child suffers an injury because of participating in this project, the public health service will provide hospital care and treatment at no cost to you.

11. Will my child be able to claim compensation if injured?

By signing the consent form, you and your child are not giving up any legal rights to seek to obtain compensation for injury.

If you would like more information about the project or if you need to speak to a member of the research team in an emergency please contact:

Name: Dr Ben Gelbart or Dr Siva Namachivayam or Professor Frank Shann

Contact telephone: (03) 9345 5211

If you have any concerns and/or complaints about the project, the way it is being conducted or your child's rights as a research participant, and would like to speak to someone independent of the project, please contact:

Director, Research Development & Ethics, The Royal Children's Hospital Melbourne on telephone: (03) 9345 5044.

CONSENT FORM

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- I have read, or had read to me in my first language, the information statement version listed above and I understand its contents.
- I believe I understand the purpose, extent and possible risks of my child's involvement in this project.
- I voluntarily consent for my child to take part in this research project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I understand that this project has been approved by The Royal Children's Hospital Melbourne Human Research Ethics Committee and will be carried out in line with the National Statement on Ethical Conduct in Human Research (2007).
- I understand I will receive a copy of this Information Statement and Consent Form.

Child's Name		
Parent/Guardian Name	Parent/Guardian Signature	Date
Name of Witness to Parent/Guardian's Signature	Witness Signature	Date

Declaration by researcher: I have explained the project to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible risks of their child's involvement in this project.

Research Team Member Name	Research Team Member Signature	Date

Note: All parties signing the Consent Form must date their own signature.