

Informed Consent Form

A Prospective Open Randomized Clinical Trial of
Non-invasive Ventilation Versus Standard Therapy for
Children Hospitalized With an Acute Exacerbation of
Asthma

NCT03296579
Protocol ID: H17-02008

September 27, 2017

SUBJECT INFORMATION AND CONSENT FORM

A prospective open randomized clinical trial of non-invasive ventilation versus standard therapy for children hospitalized with an acute exacerbation of asthma.

PRINCIPAL INVESTIGATORS:

Dr Joseph Mathew,
Assistant Professor,
Department of Pediatrics,
Post-Graduate Institute of Medical Research,
Chandigarh, India.

Dr Mike Seear,
Clinical Professor,
UBC Department of Pediatrics.
Head, Division of Respiratory Medicine.
BC's Children's Hospital,
Vancouver, Canada.

CO-INVESTIGATORS:

Dr. Mandeep Walia
Dr. David Wensley
ER physician
2 research coordinators.

LEAD INSTITUTION:

Post-Graduate Institute of Medical Research,
Chandigarh.

CONTACT NUMBERS:

EMERGENCY CONTACT:

For any emergency related to your child's asthma or related to the current study, please ask to have the on-call study coordinator paged. This service is available 24 hours a day, 7 days a week.

If you have any questions regarding this study, you may contact Dr Mathew's office.

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line ??

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. When we say “you” or “your” in this consent form, we mean you and/or your child; “we” means the doctors and other staff. Where possible, we will also request permission from your child using age-appropriate information about the study.

Introduction

You are being invited to take part in this research study because your child has recently been diagnosed with an asthma attack and requires hospitalization. Asthma is a common condition that affects the small tubes that carry air in and out of the lungs. Children with asthma develop tightened and narrowed airways when they come into contact with certain triggers. This causes a flare-up of the asthma – often called an attack, where an affected child has to struggle to breathe. In this study we will compare two different approaches for managing asthma attacks.

Background

When a person with asthma comes into contact with something that irritates their airways (an asthma trigger), the muscles around the walls of the airways tighten, the lining of the airways becomes inflamed and swollen, and the inflamed airways make more mucus than usual. These changes cause the airways to become narrowed which can lead to wheezing, coughing and breathing difficulties (an ‘asthma attack’). The most common asthma trigger in children is a viral infection.

Usually these attacks can be controlled by giving two different classes of medication. The first class includes drugs that control the inflammation in the lungs – usually a form of steroid. The second class includes drugs that relieve the narrowing of the airways so allowing the child to breathe more easily. Although these standard treatments usually work well, some children with severe asthma attacks do not respond to conventional therapy. Such cases need to be admitted to hospital for additional forms of treatment and a few will need to be admitted to the ICU so they can be ventilated (a breathing tube into the lungs connected to a machine that breathes for the child). These extra treatments used for severe cases of asthma can have unwanted side effects.

Another type of treatment that can help children with breathing difficulties is non-invasive ventilation (NIV). This involves getting the child to breathe against positive pressure delivered by a face or nasal mask. NIV works by blowing air into the airways through the nose or mouth, which helps to keep the airways open, clears mucus, and reduces the effort and energy that children use to breathe. NIV is known to be a safe and helpful treatment for a wide range of breathing problems but there is a lack of research to tell us whether it is a better treatment for children with severe asthma compared to traditional therapies.

Purpose of the Research

The purpose of this study is to compare our hospital's standard treatment for severe asthma attacks (using the classes of drugs described above), tested against early use of NIV. We hope that this will tell us whether starting NIV early in an asthma attack can make a child's breathing difficulties less severe, shorten the length of time they need to spend in hospital, and make them less likely to need to be put on a ventilator.

Your Participation is Voluntary

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to your child during the study and the possible benefits, risks and discomforts.

If you wish to take part in this study, you will be asked to sign this form. If you decide you will take part in this study, you are still free to withdraw at any time, without giving any reasons for your decision.

If you do not wish to take part, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

Please take time to read the following information carefully and consider discussing it with your family, friends, and doctor before you decide.

Who is conducting the study?

This study is being carried out at the Post-Graduate Institute of Medical Research, Chandigarh, India. The principal investigators are Dr Joseph Mathew in Chandigarh and Dr Michael Seear in Vancouver, Canada. The study is not receiving funds from an external agency or sponsor

Who Can Participate in the Research?

All children over 24 months of age with a clinical diagnosis of asthma and symptoms of a moderate or severe asthma attack.

Who cannot Participate in the Research?

Children admitted to the Intensive Care Unit directly from emergency, or who:

- have positive pressure home ventilation or a tracheostomy
- have an upper airway abnormality
- have congenital heart disease or longstanding lung disease
- are thought to have a bacterial lung infection ('pneumonia') and need antibiotics

What does this study involve?

If you agree to take part in this study you will be randomized (like a toss of a coin) to receive either receive standard asthma therapy or one of two forms of NIV therapy. In both cases, your child will wear a face mask over the mouth and nose and breathe against a constant pressure (called CPAP) or against a varying pressure (called BiPAP). You will have an equal chance of being in one of the three treatment groups (standard therapy, CPAP, BiPAP). Once you decide to join the study neither you nor your doctor will have a choice in what group you are placed in. Regardless of the group your child is randomized into, they will still receive regular ventolin inhalers and an oral steroid (a medicine that reduces inflammation in the airways) as we know that these are important medicines for children who are having an asthma attack. Once your treatment group is selected there is nothing further that is required for you to do.

Standard Treatment Arm of study:

If your child is randomized to the standard treatment arm he/she will receive care in the emergency room and once stabilized, will be transferred to the hospital ward or intensive care unit where he/she will continue to receive airway relaxing medicines, plus oral steroids and oxygen as needed via a mask, Your child will be closely monitored by nursing staff.

NIV treatment arms of study:

If your child is randomized to one of the two forms of NIV (CPAP or BiPAP), he/she will start the mask ventilation in the emergency room and once stabilized, will be transferred to a medical ward for close observation. Your child will continue to receive an airway relaxing drug (salbutamol) and oral steroids, but will also receive oxygen as needed via the NIV machine. The duration of NIV treatment will be about 12 to 48 hours. Your child will also be closely watched by the nurses.

The following information will be collected from your child's medical record once your participation is complete:

- Age and gender
- Weight and length
- Past medical history
- Family history of asthma
- Household smoking
- Any viruses found in secretions
- Any additional treatments used during the admission
- Your child's breathing rate over the course of the admission
- The length of hospital stay
- The amount of airway-relaxing medicines they need during their hospital stay

Risks and Discomforts

NIV therapy involves breathing against positive pressure through a face mask. This is an unfamiliar sensation so a few children take time to become accustomed to the tight fitting mask and extra pressure during breathing. We start by explaining the technique carefully and build up the pressure slowly. Almost all children are able to tolerate these procedures without significant discomfort.

Short term minor side effects may include dryness of eyes and mouth, mild skin irritation from the mask and mild, self-limiting abdominal distension secondary to the pressure in the mask.

The only potential significant side effect is a leak of air from the lungs caused by the mask pressure. This is called a pneumothorax. While it is a theoretical problem, there have been no reports of a pneumothorax associated with the use of BiPAP in children treated for asthma. To minimize this small risk, we use the minimum pressure necessary to keep your asthma controlled.

Signing this consent form in no way limits you or your child's legal rights against the investigators, or anyone else and, by signing this consent form, you do not release the study doctors or participating institutions from their legal and professional responsibilities.

Potential Benefits

You may not receive any benefit from taking part in this research study. We hope that the information learned from this study will improve our ability to treat asthma in the future.

What are the alternatives to the study treatment?

If you choose not to participate in this study or withdraw at a later date, your child will receive standard care for asthma that follows established hospital treatment protocols. You are encouraged to discuss this with your doctor before deciding whether or not to participate in this research project.

What will the Study Cost me?

There is no cost to you to participate in this study. Please note you will not be paid if you choose to take part in this study.

New information that we get while we are doing this study may affect your decision to take part in it. If this happens, we will tell you about this new information, and we will ask you again if you still want to be in the study.

What happens if I decide to withdraw my consent to participate?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time without giving reasons.

If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis, the data cannot be withdrawn.

What if new information becomes available that may affect my decision to participate?

If you choose to enter into this study and at a later date a more effective treatment becomes available, it will be discussed with you. You will also be advised of any new information that becomes available that may affect your willingness to remain in the study.

Confidentiality

Your child's confidentiality will be respected. However, research records and medical records identifying your child may be inspected in the presence of the Investigator or his or her designate by representatives of the hospital's Research Ethics Boards. No information or records that disclose your child's identity will be published without your consent, nor will any information or records that disclose your child's identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity (i.e. your name or any other identification information), that could identify your child as a subject in this study, will be kept confidential.

Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique identifier that is used on your research-related information will not be removed or released without your consent unless required by law.

You and your child's rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected and also give you and your child the right of access to the information about you and your child that has been provided to the investigator, and if need be to correct any errors in this information. Further details about these laws are available on request to your study doctor.

PARTICIPANT'S CONSENT TO PARTICIPATE IN RESEARCH

My signature on this consent form means:

I have read and understood the subject information and consent form.

I have had sufficient time to consider the information provided and to ask for advice necessary.

I have had the opportunity to ask questions and have had satisfactory response to my questions.

I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objective.

I understand that participation in this study is voluntary and that I can completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.

I understand that I am not waiving any of my legal rights or my child's as a result of signing this consent form.

I have read this form and I freely consent to participate in this study.

I have been told that I will receive a dated and signed copy of this form.

☐ I would like to be contacted about participating in future research studies.

Name of Participant: _____

Printed name of
Legally Acceptable
Representative/or participant

Signature

Date
(dd-mmm-yyyy)

Printed name of Person
Conducting Informed Consent
Discussion

Signature

Date
(dd-mmm-yyyy)