Dose escalation clinical trial of high -dose oral montelukast to inform future RCT in children with acute asthma exacerbations

NCT 05819541

Assent ages 7-12 years

5.21.25

PI: Donald H. Arnold, MD, MPH **Version Date:** 05.21.25

Title of Study: Dose escalation clinical trial of high-dose oral montelukast to inform future RCT in children with acute asthma exacerbations **Hospital**: Vanderbilt Children's Hospital

This assent document applies to: Children ages 7 - 12 years

Name of participant _____ Age_

Below are the answers to some of the questions you may have. If you have any questions about what is written below or have any other questions about this research, please ask them. You will be given a copy of this consent form. We use some big words. Please ask me to explain any that you do not understand.

1. **Why are we doing this research?**
You are being asked to be in this research because you are having an asthma attack. We want to find out if a medicine called montelukast will help kids with asthma attacks feel better. The way we do the research is called a Phase 2, randomized, double-blind clinical trial. Phase 2 means we are using montelukast in a new way to see if it makes you feel better. Randomized means there is an equal chance you will get the medicine or a liquid that looks and tastes the same. Double-blind means we and you will not know if you got the montelukast or the sugar solution.
If you want to do this, we will ask you and your parent to answer 2 questions about any feelings you have about hurting yourself. We will ask your parent some questions about any worry or upset feelings you have had. These questions will tell us if you can be in the research.

2. **What will I do and how long will it take?**
We will take your height and weight and will listen to your lungs. We will ask you to do a breathing test now and 4 more times if you are still in the hospital. The breathing test will not hurt you or keep you longer in the hospital. You will breathe through a mouthpiece for about 30 seconds and do this 3 times. The total time for the research will be about 40 minutes during your ER stay.
Some children in the study will get montelukast and others will get a sugar liquid. You and we will not know if you got montelukast or the sugar liquid. They will look and taste the same We will then ask you to swallow some water. If you get montelukast, how much you get will be based on how big you are.
We will ask your parent 7 special questions The questions are called the child asthma control test or c-ACT. The questions help us to know how much trouble your asthma has been causing you. This is for the past 3 months. We will ask your parent 7 – 14 days from now to answer questions about any symptoms of being sick or any worry, sad, or upset feelings you have had.
We will gently swab your nose with a "Q-tip." We use this to see if things called viruses are there. Viruses sometimes cause asthma attacks. We will take blood samples from the IV "straw" that the nurses put in your arm. This will be before the medicine and again at 2, 3, 4, 8, 12-18, and 18-24 hours if you are still in the hospital.
After you finish the study, we will send your parent a check for $150. This is to pay for the time and work you and your parent helped with for the research.

3. **Do I have to be in this research? Can I stop if I want to?**
You may do not have to help with this research. If you do not want to, it will not change how the doctors and nurses care for you. You can stop being in the research at any time by just telling us that. We will tell you if we learn something new that can change the risks or good things that can happen from this research. This will help you decide if you still want to be in this research.

4. **Could it make me sick [or sicker]?**

Children who take more than 10-times the daily montelukast dose every day have no more stomachache or other hurtful effects than those who take the usual daily dose. We have learned that children taking more than 50mg of montelukast or 10-times the usual dose have the following hurtful effects:

Common hurtful effects are those that happen in more than 10 out of every 100 children taking montelukast every day. We do not think common side effects will occur with the dose used for this research.

Uncommon hurtful effects are those that happen in between 1 and 10 out of every 100 children taking montelukast every day. These include stomachache and throwing up.

Rare side effects are those that happen in less than 1 out of every 100 children taking montelukast every day. These included head hurting, nausea, dizziness irritability, loose poops, rash, and fast heart rate.

But there have been worries that some children taking montelukast at the 5 mg dose every day begin having problems with their feelings. These have included getting fidgety, really angry, worried, feeling sad, not knowing where they are, not paying attention, strange dreams, stuttering, seeing or hearing things that are not really there, trouble sleeping, being fussy, memory problems, bad thoughts called obsessions and compulsions, restlessness, sleep walking, thoughts of hurting or killing themselves, and attempts to kill themselves. **We will ask your parent to call Dr. Arnold as soon as they can if any of these happen.**

5. Will anyone know that I am in this research study?

We will do our best to keep anyone else from learning things like your name, birthday, and where you live but we cannot promise this will not happen. We will share your name and other things with some people at the hospital who need to know, if you or someone else is in danger, or if we have to because of a law. We will keep the research results for at least six years after the research is completed. At that time, the research information not already in your medical record will be destroyed. Any research information entered into your medical record will be kept for a lot longer.

6. How will this research help me or other people?

Other people might be helped by this research by using montelukast to make asthma attacks in children better fast enough to keep them from being in the hospital. We may contact you about being in future research.

7. Can I do something else instead of this research?

You do not have to be in this research at any time. You just need to tell us that you don't want to. There will be no change in the care you get from the doctors and nurses if you stop being in the research.

8. Who do I talk to if I have questions?

If you have any questions about this research or if you feel you have been hurt by being a part of this study, please ask you mom or dad to call **Dr. Donald H Arnold** at **615-936-4498 (office) and leave a voicemail or call his pager at 615-831-6115.**

For additional information about giving consent or your rights as a person in this study, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273, or email at http://mcapps01.mc.vanderbilt.edu/IRB/WkshpReg.nsf/Suggestion Form?OpenForm.

Date Signature of patient/volunteer

Consent obtained by: _____

Signature Printed Name and Title