

Assent to Participate in a Research Study (12 – 17 years of age)

Who are we and what are we doing?

We are from Primary Children's Hospital and we would like to ask if you would be in a research study. A research study is a way to find out new information about something. This is the way we try to find out if the study medicine is safe and if it works.

Why are we asking you to be in this research study?

We are asking you to be in this research study because we want to learn more about how the study medication works in young people with a complicated intra-abdominal infection. The study medication is called <<study drug>>. It will be compared to another medication available by prescription called <<drug name>>.

About 120 young people will participate in this study.

What happens in the research study?

If you want to be in this study and your parents and doctor agree, you will first complete a screening visit. During screening, some tests will be done to see if you can be in this study. During the study we will check and perform the following things:

- We will check your blood pressure, breathing & heart rate, temperature, height & weight and do a physical exam
- We take blood and urine samples to check for certain tests for your safety. It may hurt when the needle is put into your arm but it may be possible to draw the blood at the same time as the IV is put so that you may not need another needle stick
- We will give you the study medicine through an IV (plastic tube) in your arm
- If you are a girl and have started your monthly periods, your doctor will talk with you about not getting pregnant. Some of your blood and urine will also be checked to make sure you are not pregnant
- You will be in the study for about 5-7 weeks

While you are in the study you must:

- Give correct information about your medical condition in the past and current medical condition.
- Tell the study doctor about any health issues you have during the study.
- Tell the study doctor about any new medicine or drug you take during the study.

- Not take any other medicines or remedies unless the study doctor has approved them beforehand. This includes prescription drugs and over-the-counter medicine (including vitamins and herbal remedies) that you buy without a prescription.
- Come to all appointments
- Not participate in other research studies.
- Not get pregnant or cause your girlfriend to become pregnant.
- Take study drug(s) at the hospital by intravenous (IV) infusion.
- You will be assigned by chance to get either:
 - <<study drug>>
 - <<drug name>> + placebo (look-alike with no active ingredients)

Other Treatments

Instead of taking part in this study, you may choose that you receive standard treatment or other treatments prescribed by your doctor.

Alternative treatments include other approved antibiotics for intra-abdominal infections.

Your study doctor will explain the good and bad things that could happen with these other treatments and will answer any question you may have.

Will any part of the research study hurt you?

There is a chance that during this research study you could feel afraid, uncomfortable, or hurt. We will try to help you feel better if this happens. You can stop at any time if you want to.

You could have some side effects while taking the study medicine(s). (Side effects are things that happen that may not be expected, or are not wanted.) Some grown-ups and kids who took these medicines experienced:

- Rash
- Fever
- Low blood pressure
- Trouble going to the bathroom
- Changes in blood test results
- Trouble falling and/or staying asleep
- Worry
- Feeling sick to your stomach
- Throwing up
- Headache
- Feeling dizzy

- Diarrhea
- Stomach pain
- Pain in the arm where the plastic tub & needle is placed for the Ceftolozane
- Mouth pain & swelling
- Strange taste
- Dry mouth
- Yeast infection
- Not feeling like eating as much
- Constipation
- Pain and swelling
- Hard time breathing
- Itching
- Bleeding

These things may or may not happen to you. If you have any of these happen to you, or if you feel pain, or do not feel well tell your parents and your study doctor right away. They may decide that it is best for you to stop taking the study medicine. Your study doctor will check on you and try to help you feel better.

What about birth control and pregnancy during the study?

If you are a girl, you cannot take part in this study if you are pregnant or breast-feeding a child. You must agree not to become pregnant while you are in this study. If you do get pregnant and take the study medicine, you could harm your unborn child or breast-fed baby.

If you are a girl, who has started menstrual periods and is having sex, your study doctor will talk with you about methods of birth control.

If you get pregnant during the study, you must tell the study doctor **immediately**. You will have to stop the study medicine. You may need to come to the study clinic for follow-up safety visits. The study doctor will advise you about your medical care and will ask you to allow him or her to collect information about your pregnancy and the health of your baby.

If you are a boy, the effect of the study medicine on your sperm is unknown. If you are having sex, from when you start taking the study medicine until 6 month(s) after your last dose, you and/or your girlfriend must use an approved form of birth control to prevent your girlfriend from getting pregnant.

If your girlfriend becomes pregnant, while you are on the study medicine or for 6 months after the last time you got the study medicine, you must tell the study doctor

immediately. Your study doctor will ask you and your girlfriend to allow him/her to collect information about your girlfriend's pregnancy and the health of your baby.

Will the research study help you or anyone else?

We do not know for sure if being in this research study will help you. It is possible that we could learn something to help other people someday.

Who will see the information about you?

Only the researchers in this study or people from the company that makes the study medicine, the people working for them, or someone who oversees the study will be able to see the information about you from this research study this is to make sure the study is being done properly.

If you are a girl and we find out that you are pregnant, we will talk with you about this and help you tell your parents.

What if you have any questions about the research study?

It is okay to ask questions. If you don't understand something, you can ask us. We want you to ask questions now and anytime you think of them. If you have a question later that you didn't think of now, you can call <<PI name>> and <<phone number>> or ask us the next time we see you.

You may call at any time to ask questions about your disease or treatment.

Do you have to be in the research study?

You do not have to be in this study if you don't want to. Being in this study is up to you. No one will be upset if you don't want to do it. Even if you say yes now, you can change your mind later and tell us you want to stop.

You can take your time to decide. You can talk to your parent or guardian before you decide. We will also ask your parent to give their permission for you to be in this study. But even if your parent or guardian say "yes" you can still decide not to be in the research study. Your doctors will continue to take care of you even if you decide not to be in this research study.

If you leave the study before you have completed it, you may be asked to return to the study doctor to have final tests done for safety reasons.

Your study doctor or the company that makes the study medicine can take you out of the study. This can happen at any time with or without your agreement. These decisions will be made if either believes that:

- It is in your best medical interest to stop your participation.
- You need treatment not allowed in this study.
- You do not follow instructions.
- The study is cancelled.

Agreeing to be in the study

I was able to ask questions about this study. Signing my name at the bottom means that I agree to be in this study. My parent or guardian and I will be given a copy of this form after I have signed it.

Printed Name

Sign your name on this line

Date

Printed Name of Person Obtaining Assent

Signature of Person Obtaining Assent

Date

The following should be completed by the study member conducting the assent process if the participant agrees to be in the study. Initial the appropriate selection:

_____ The participant is capable of reading the assent form and has signed above as documentation of assent to take part in this study.

_____ The participant is not capable of reading the assent form, but the information was verbally explained to him/her. The participant signed above as documentation of assent to take part in this study.

SAMPLE