

Concise Summary

This is a research study to find out if a drug called ABC-123 is safe and to determine the safest, most effective dose of the drug. Participation in research studies is voluntary.

Depending on when you enroll in this study, you will receive higher doses of ABC-123 until the safest and best tolerated dose is reached. ABC-123 is given via *i.v.* infusion in the clinic at Duke. You will have tests, exams and procedures that are part of your standard care and for study purposes. Each clinic visit will last 4-5 hours. Infusions of study drug will be given during week 1 of each 3-week cycle. After two cycles, you will be evaluated and you may be able to continue receiving ABC-123 if you have had no bad reactions to the study drug or disease progression.

There are risks to this study drug that are described in this document. Some risks include: nausea, diarrhea, low white & red blood cell count, being tired & weak, fever, muscle pain and radiation risks from CT scans. We hope that, in the future, the information learned from this study will benefit others with your condition. You do not have to participate in this research to be treated for your condition. Your personal healthcare provider can discuss alternatives, including other drugs such as XYZ and JKL.

If you are interested in learning more about this study, please continue reading below.

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The purpose of this research study is to determine the effectiveness of physical therapy in the treatment of patients with ABC. Participation in research studies is voluntary. In this study, participants will undergo a 2-day screening that includes a blood draw, exercise testing, and completion of quality-of-life surveys. Once screening is complete, participants will complete a physical therapy program that will require visits to Duke's fitness center three times each week for 16 weeks, for a total of 48 visits. Each visit will take about 2 hours. Participants will also be asked to complete a pain diary and have blood draws every 4 weeks throughout the study. Follow-up phone calls from the study team will occur at 4 weeks and 8 weeks after completion of the physical therapy program. Total study duration is about 6 and one-half months.

The greatest risks of this study include the possibility of injury during the physical therapy program and loss of confidentiality. The potential benefits of this study are reduction in your pain due to ABC, and improved symptom management and mobility.

Instead of being in this study, you have the following alternatives for treatment of the pain of ABC, such as medication, hot and cold therapy, and acupuncture. Please talk to your doctor about these and perhaps other options.

If you are interested in learning more about this study, please continue to read below.

Concise Summary

The purpose of this research study is to compare the gastrointestinal (GI) tract in children with Inflammatory Bowel Disease (IBD) and healthy children. The information we learn by doing this study may help us to develop some target treatments for GI complications in children with IBD. Your child's participation is voluntary.

Participants in this study will have a blood sample collected and a small piece of tissue removed from their intestine during their clinically scheduled procedure. The comparison of tissue from IBD and healthy children will be done in the laboratory after collection of the tissue. Parents of participating children will also be asked to complete a questionnaire. Your child's participation is complete once the medical record and questionnaire have been reviewed, and the tissue and blood sample have been collected.

There is a risk of bleeding after the tissue from the intestine is removed. Risks of taking the blood sample are discomfort and/or bruising; infection, excess bleeding, clotting, or fainting are also possible. This study does not provide a direct benefit to your child, but may benefit other children with IBD in the future.

If you are interested in learning more about this study, please continue to read below.