MRCP: A Reliable, Non Invasive Method for Staging Chronic Pancreatitis in Pediatrics

Parental Permission Document

NCT02869893

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STUDY TITLE: Magnetic Resonance Cholangiopancreatography (MRCP) A Reliable, Non Invasive Method for Staging Chronic pancreatitis from Minimal Change Disease to the Advanced Stages in Pediatrics

STUDY NUMBER: 2016-2847

FUNDING ORGANIZATION: National Pancreas Foundation

Principal Investigators: Maisam Abu-El-Haija, MD
Andrew Trout, MD

Telephone Number: 513-803-2123

INTRODUCTION

We are asking for your permission for your child to be in a research study so that we can learn new information that may help others. If you decide not to give your permission for your child to be in this study, we will still take good care of him/her. If you decide to allow your child to be in this study, you may change your mind at any time during the study and your child can stop being in the study. Take all the time you need to make your choice. Ask us any questions you have. It is also okay to ask more questions after you decide to allow your child to be in the study. You can ask questions at any time.

WHY ARE WE DOING THIS RESEARCH?

We are asking your child and other children *without* pancreatic diseases to be in this research study because we need to better understand what the pancreas looks like in healthy children so that we can take better care of children with pancreas diseases.

In this research study we want to learn more about the pancreas. We want to use Magnetic Resonance Cholangiopancreatography (MRCP) to learn more about the size of a normal pancreas. MRCP is a special kind of Magnetic Resonance Imaging (MRI) exam that produces detailed pictures of the pancreas. We also want to figure out how much fluid the pancreas releases in response to secretin. Secretin is a chemical in the body that helps with digestion. We use secretin during the MRCP (MR-PFT) to help us find dysfunction of the pancreas. We will also measure how hard the pancreas is by using MR elastography (MRE). MRE is a special kind of MRI that uses vibrations to image tissue.

We have successfully performed both MR-PFT and MRE in patients with chronic pancreatitis.

WHO IS IN CHARGE OF THE RESEARCH?

Maisam Abu-El-Haija, MD is the researcher at Cincinnati Children's Hospital Medical Center (CCHMC) that is in charge of this study.

CCHMC is being paid by The National Pancreas Foundation (a non-profit foundation) to do this study with about 50 children.

WHO SHOULD NOT BE IN THE STUDY

Your child cannot be in this study if he/she has any of the following:

1. A history of pancreatic disease, liver disease, abdominal tumor, inflammatory bowel disease (IBD), or cystic fibrosis.
2. Surgically implanted devices making them ineligible for MRI (e.g. pacemaker).
3. Pregnant or less than 12 months post-partum.

WHAT WILL HAPPEN IN THE STUDY?

You will be able to ask questions to make sure that you understand what will happen to your child.

If your child qualifies and you decide you want your child to be in the study, your child will come to CCHMC for one visit. If your child is a girl who has started having periods, we will do a urine pregnancy test. Pregnant people cannot be in this research. We will share the results of the pregnancy test with you and your child.

These are the things that will happen to your child while in the study:

MR-PFT and MRE exams will be performed on an MRI scanner. Your child will not be able to eat or drink for four hours before the visit. The MRI technologist will place the IV in your child's arm at the beginning of the exam. Your child will then be placed into the scanner. Your child may request video goggles for entertainment during the exam. All pre-secretin imaging will be performed first. Next, a study team doctor or nurse will inject the secretin through the IV and all post-secretin imaging will be performed. After that, your child will be removed from the scanner and the IV will be removed.

The MR imaging will take about 35 minutes. Your child will be in the room for about 50 minutes total.

After all imaging is obtained, imaging data will be de-identified for analysis for this study and will be kept in de-identified form for potential future study. De-identified means we will remove all personally identifying information such as name or medical record number.

WHAT ARE THE GOOD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

Being in this study may not help your child right now. When we finish the study, we hope that we will know more about using MRI to learn about the pancreas. This may help children with chronic pancreatitis later on.

WHAT ARE THE BAD THINGS THAT CAN HAPPEN FROM THIS RESEARCH?

There are no known risks from having an MRI or from studying the use of the pictures from the MRI.

However, some people are claustrophobic and may become anxious, fearful, or nervous in the MR scanner. **If your child becomes uncomfortable at any time the scan will be stopped immediately**.

We will use an IV, which may cause some pain, bleeding, or bruising at the site. There is a small chance for infection.

Secretin may cause abdominal pain, nausea, or flushing. These effects are minor and can be easily monitored.

There may be other risks that we do not know about yet.

WHAT OTHER CHOICES ARE THERE?

Instead of being in this study, you can choose not to have your child be in it.

HOW WILL INFORMATION ABOUT YOUR CHILD BE KEPT PRIVATE?

Making sure that information about your child remains private is important to us. To protect your child's privacy in this research study, data that we collect will be stored in locked rooms and password protected files. As soon as we have finished collecting data on all of the participants, we will separate identifying information about your child from the data we are collecting. Identifying data will be saved in a password-protected database. Only the primary investigators and select study personnel will have access to information that might be used to identify you.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify your child. At most, the website will include a summary of the study results. You can search this website at any time.

WHAT IF WE LEARN NEW INFORMATION DURING THE RESEARCH?

The study doctor will tell you if they find out about new information from this or other studies that may affect your child's health, safety or your willingness for your child to be in this study. The results of this study will not be made available to you. A member of the study team will notify you if we identify clinically significant abnormalities.

WILL IT COST YOU ANYTHING EXTRA FOR YOUR CHILD TO BE IN THE RESEARCH STUDY?

You or your insurance company will not be charged for the research MRI. Your insurance company will be charged for your continuing routine medical care including tests and treatments required for your clinical care.

WILL YOU/YOUR CHILD BE PAID TO BE IN THIS RESEARCH STUDY?

You (your child) will be reimbursed for your time, effort and travel while you are in this research study.

You will be paid $100 at the end of the study visit upon completion of the MRI exam in the form of a reloadable debit card (Clincard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, CCHMC is required by the Internal Revenue Service (IRS) to collect and use your (or your child's) social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your child's Social Security number. This form will be given to the CCHMC business office. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

WHAT HAPPENS IF YOUR CHILD IS INJURED FROM BEING IN THIS STUDY?

If you believe that your child has been injured as a result of this research you should contact Maisam Abu-El-Haija, MD (513-803-2123) as soon as possible to discuss the concerns.

CCHMC follows a policy of making all decisions about compensation for the medical treatment of physical injuries that happened during or were caused by research on an individual basis.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

For questions, concerns, or complaints about this research study you can contact the study doctor listed on page 1 of this document.

If you would like to talk to someone that is not part of the research staff or if you have general questions about your research study rights or questions, concerns, or complaints about the research, you can call the CCHMC Institutional Review Board at 513-636-8039.

WHAT ELSE SHOULD YOU KNOW ABOUT THE RESEARCH?

The research MRI exams (MR-PFT and MRE) that are being done in this study are the same as MRI exams we do routinely at CCHMC.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your child's "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?
CCHMC will need to use and share your child's PHI as part of this study. This PHI will come from:

- Your child's CCHMC medical records
- Your child's research records

The types of information that will be used and shared from these records include:

- Laboratory test results, diagnosis, and medications
- Reports and notes from clinical and research observations

- Imaging (like CT scans, MRI scans, x-rays, etc.) studies and reports
- If applicable, information concerning HIV testing or the treatment of AIDS or AIDS-related conditions, drug or alcohol abuse, drug-related conditions, alcoholism, and/or psychiatric/psychological conditions (but not psychotherapy notes).

Who will share, receive and/or use your child's protected health information in this study?

- Staff at all the research study sites (including CCHMC)
- Personnel who provide services to your child as part of this study
- Other individuals and organizations that need to use your child's PHI in connection with the research, including people at the sponsor and organizations that the sponsor may use to oversee or conduct the study.
- The members of the CCHMC Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your child's PHI is not misused?

People that receive your child's PHI as part of the research are generally limited in how they can use your child's PHI. In addition, most people who receive your child's PHI are also required by federal privacy laws to protect your child's PHI. However, some people that may receive your child's PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your child's PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share your child's PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about your child will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your child's other medical care be impacted?

By signing this document you agree for child to participate in this research study and give permission to CCHMC to use and share your child's PHI for the purpose of this research study. If you refuse to sign this document your child will not be able to participate in the study. However, your child's rights concerning treatment <u>not</u> related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether your child should participate in this research you will document your permission by signature below.

You will receive a copy of this signed document for your records.

_____
Printed Name of Research Participant

_____ _____
Signature of Research Participant Indicating Consent or Assent — Date

_____ _____
Signature of Parent or Legally Authorized Representative* — Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent — Date