Title of research study: Post-ERCP Pancreatitis Prophylaxis, Effectiveness of Rectal Indomethacin vs Intravenous Ketorolac in the Pediatric Population

Key Information:

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

If you are 18 years and older: This is a consent form. It explains this research study. If you decide that you want to be in this research study, then you will sign this form to show that you agree to be part of this study. If you sign this form, you will receive a signed copy of it for your records.

Parents/Guardians: You have the option of having your child or teen join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

Investigator:
David S. Vitale, MD.

Contact Info:
Ethan Estes
(513)803-4322

Protocol #:
2022-0640

Drug Name(s):
Indomethacin
Ketorolac

Funding: *Division of Pediatric Gastroenterology, Hepatology and Nutrition*

COMBINED Parental Permission/Assent: If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this form, we mean you or your child; "we" means the study doctor and other staff.

Reason for the study:

Endoscopic retrograde cholangiopancreatography (ERCP) is an essential procedure that can be complicated by post-ERCP pancreatitis (PEP). Indomethacin and ketorolac are two medications used to prevent PEP. The main reason for this research study is to compare the effectiveness these drugs at reducing rates of PEP. There have been no studies comparing the effectiveness of these medications in preventing PEP in pediatric patients. You are being asked to take part in this research study because you are scheduled to have an ERCP as part of your medical care.

Procedures:

If you qualify and you decide to be in the study, you will not have to stay in the hospital for any longer than is needed to complete your clinical care, and will not have to come back for follow up visits for this study.

You will be "randomized" into one of 2 study groups. Being randomized means you will be put into a study group by chance, like flipping a coin. You will have a 50-50 chance of being given either treatment:

- Intravenous (IV) ketorolac
- Rectal indomethacin

Neither you nor the researchers conducting this study will know, ahead of time, what group you are being placed into. However, once treatment has started, everyone, including you will know which drug you receive.

The following procedures will be done as the standard of care after the ERCP and will be performed even if you do not choose to take part in the research:

- You will be given IV fluids.
- You will only be able to have clear liquids until you are able to eat solid food comfortably.
- You will get at least 3 pain assessments. A nurse will complete these assessments while you are admitted after the ERCP.
- If pain or nausea occurs, the primary doctor will order a standard set of lab work (blood tests). If you meet criteria for PEP, you will remain on IV fluids and your diet will be returned to a clear liquid diet.

Data from the results of these standard of care procedures will be collected from your medical record for research purposes for about 2 weeks after your ERCP.

You may be contacted for future research.

Optional Samples: At the end of the consent you can indicate your preference regarding the collection of blood samples for research. We would like to collect up to three blood samples per ERCP-related appointment or admission for up to 24 months following your enrollment. We will try to coordinate the blood collection to occur at the time of a clinical blood sample or procedure. Blood will be stored and used for genetic and disease biomarker studies.

All samples and data collected for this study will be given a unique code and stored in a secure location to which only our study team has access. No identifying information will be published.

Risks to Participate:

Both indomethacin and ketorolac are standard of care treatments. However, the risks associated with each medication are listed below. Being in this research study will not increase the risk of either treatment.

<u>Ketorolac adverse reactions:</u>

- Belly pain

- Indigestion
- Nausea
- Headache

Indomethacin adverse reactions:

- Vomiting
- Postoperative bleeding
- Headache

Risk of loss of confidentiality:
Every effort will be made to keep your personal information confidential. Please see the section titled “Privacy” in this consent form for detailed information on how your information will be protected.

Benefits to Participate:

There are no benefits to you from your taking part in this research. However it can help other children in future by improving outcomes for patients after an ERCP.

Other Options:

Both of these drugs are considered standard of care treatment, but participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you receive. Your alternative to participating in this research study is to not participate.

Cost to Participate:

You and your insurance company will be charged for the healthcare services that you would ordinarily be responsible to pay. Costs associated with research only blood samples will be covered by the research study. There are no additional costs to take part in this research study.

Payment:

You will not receive payment for taking part in this study**.**

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Dr. David Vitale**	Phone: (513) 803-2123
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Ethan Estes**	Phone: (513)803-4322
• Your rights as a research participant	**Institutional Review Board (IRB)** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: (513) 636-8039

Change of Mind/Study Withdrawal:

You can leave the research at any time; it will not be held against you.

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the Institutional Review Board (IRB) and other representatives of this organization. An IRB is a group of scientists and non-scientists who look at research projects like these and make sure research participants' rights and welfare are protected. Data collected for or generated from this study could be shared and used for future research. Data may be shared with other collaborators at Cincinnati Children's and possibly with outside collaborators, who may be at another institution or for-profit company. Only de-identified data will be shared. All future researchers will be given the least amount of information needed to meet the goals of their research project. Researchers that use this information must agree to never try to re-identify a

participant from a coded dataset. Researchers will only be allowed to use the provided information for approved research purposes. If information that could identify you is removed from your information collected during this research, that information could be stored and used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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 you. At most, the Website will include a summary of the results. You can search this Website at any time.

Return of results:

Most tests done on samples or images obtained in research studies are only for research and have no clear meaning for healthcare. If the research with your information or samples gives results that do have meaning for your health, the researchers will not contact you and ask you if you would like to know what they have found.

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 "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your Cincinnati Children's medical records
- Your 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

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

- Staff at the research study site (Cincinnati Children's)
- Personnel who provide services to you as part of this study

- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your 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 PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share 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 you 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.

Will your other medical care be impacted?

By signing this document, you agree to participate in this research study and give permission to Cincinnati Children's to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment not 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 you 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.

Patient Name: _____Date of Birth: _____
First MI Last

Study Involvement: In regards to my research study participation,

- ☐ Initials: _____ I agree to the collection of blood samples for research **OR**
- ☐ Initials: _____ I do **NOT** agree to the collection of blood samples for research

_____ _____
Signature of Research Participant Indicating Assent or Consent 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