Informed Consent Form

Comparison between local cryoprevention associated with NSAIDs versus NSAIDs alone for reducing the incidence of post-ERCP pancreatitis: a randomized clinical trial.

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HOSPITAL DAS CLÍNICAS DA FACULDADE DE MEDICINA DA UNIVERSIDADE DE SÃO PAULO - HCFMUSP

INFORMED CONSENT FORM

Research title: "Comparison between local cryoprevention associated with NSAIDs versus NSAIDs alone for reducing the incidence of post-ERCP pancreatitis: a randomized clinical trial."

INVITATION TO PARTICIPATE:

Dear Sir/Madam, you are being invited to participate in a scientific study that seeks to evaluate a new method to prevent inflammation of the pancreas (pancreatitis) following an ERCP (Endoscopic Retrograde Cholangiopancreatography) examination.

JUSTIFICATION AND OBJECTIVES OF THE STUDY:

Inflammation of the pancreas (pancreatitis) is the most common complication following the ERCP procedure. Currently, the standard of care to prevent it is the rectal administration of a medication called a non-steroidal anti-inflammatory drug (NSAID) (insertion of a medicinal suppository through the anus after the patient is anesthetized and asleep). The objective of this study is to determine whether the application of cold distilled water (between 4ºC and 5ºC) directly to the procedure site (in the region called the major duodenal papilla), combined with the use of the anti-inflammatory drug, is more effective than using the medication alone.

PROCEDURES TO BE PERFORMED AND METHODS TO BE EMPLOYED:

If you agree to participate, you will be randomized (like a "coin toss") into one of two groups:

1. **Control Group: Will receive the standard treatment (routine ERCP + rectal NSAID)**
2. **Intervention Group: Will receive the standard treatment and, at the end of the examination, the physician will inject 250 ml of cold distilled water into the region of the duodenal papilla through the endoscope itself.**

The procedures will be performed under sedation or general anesthesia, in accordance with the institution's current practice. All participants will receive intravenous hydration and the anti-inflammatory drug indomethacin (100 mg) rectally, according to the hospital's routine. Following the examination, blood tests will be collected, if necessary (in the event of abdominal pain, nausea,

vomiting, suspected pancreatic inflammation, or suspected bleeding), and medical monitoring will be provided. All endoscopic procedures will be performed at the Gastrointestinal Endoscopy Service of the Hospital das Clínicas (6th floor of the outpatient building).

EXPLANATION OF POSSIBLE DISCOMFORTS AND RISKS ARISING FROM PARTICIPATION IN THE RESEARCH

The cold water intervention is considered low risk, being practically negligible within the context of the procedure. However, as with any ERCP, there are general risks such as abdominal pain, inflammation of the pancreas (pancreatitis), bleeding, biliary tract infection (cholangitis), or, rarely, bowel perforation. The water infusion will be performed with aspiration to prevent stomach distension. Any potential complications will be promptly treated by the Hospital das Clínicas team. It is not expected that you will develop any health problems as a result of your participation. However, as with any medical procedure, adverse events may occur and will be managed at the Hospital das Clínicas of FMUSP.

EXPECTED BENEFITS FOR THE PARTICIPANT

The main advantage of your participation is the substantial reduction in the risk of pancreatic inflammation (post-ERCP acute pancreatitis), the most common and potentially severe complication of this procedure. Post-ERCP pancreatitis causes intense pain, prolonged hospitalization, and, rarely, severe sequelae or life-threatening risks. The protocol under study aims to minimize the incidence of this inflammation, providing a potential immediate clinical advantage by reducing discomfort, pain, and the need for additional treatments or new hospital admissions. In addition to the direct benefit, your contribution is vital for the advancement of medical knowledge, potentially leading to better practices and more effective safety protocols in ERCP, thereby benefiting future patients.

REGARDING YOUR PARTICIPATION:

Your participation in the study is voluntary. You may choose not to participate or to withdraw your participation at any time, without any prejudice to the continuation of your treatment. There will be no personal expenses for the participant at any stage of the study, including examinations and consultations. The researchers may interrupt your participation at any time if they determine it is in the best interest of preserving your health, if you fail to follow the study instructions, or if you experience a serious or severe adverse event. If there are modifications to the study protocol and any significant findings emerge that may affect your health, you will be informed, and your consent will be obtained again. You will retain one of the copies of this form (ICF) after signing it. All personal

information, medical history, and examination results will be kept confidential, in compliance with Resolution No. 466/2012, Law No. 14.874/2024, and other current regulations regarding ethics in research involving human subjects. Such information will be stored in the Institution's own system, access to which is restricted to affiliated professionals, thereby preserving the patient's identity. In this regard, the privacy of your medical record will be ensured through the use of assistive technologies that promote the security and confidentiality of your data, adopting protection measures such as the use of secure connections, data encryption, and the establishment of information access levels, among other risk management precautions. This Form, despite ensuring the adoption of the aforementioned procedures, does not exempt the patient from the duty of care and protection regarding their own data. The data obtained will be analyzed collectively with that of other patients, and no patient's identity will be disclosed. Likewise, it is guaranteed that the participant will receive an identical copy of this duly signed consent form. There will be no personal expenses for the participant at any stage of the study, including examinations and consultations. Compensation is guaranteed for any patient expenses arising from any research-related harm. There is no financial compensation related to your participation.

REGARDING FOLLOW-UP AND ASSISTANCE:

At any stage of the study, you will have access to the professionals responsible for the research to clarify any doubts. The primary executor is Dr. Mateus Bond Boghossian, who can be reached at Av. Dr. Enéas de Carvalho Aguiar, 255, Prédio dos Ambulatórios, 6th floor, room 3, ZIP Code 05403-000, Telephone(s) 11-2661-7579, 2661-6221, or by e-mail endoscopiahcfmusp@gmail.com. If you have any considerations or questions regarding the ethics of the research, please contact the Research Ethics Committee (CEP) – Rua Ovídio Pires de Campos, 225 – 6th floor – tel: (11) 2661-7585, (11) 2661-1548, from 7 am to 4 pm, Monday to Friday, or by e-mail: cappesq.adm@hc.fm.usp.br. All patients participating in this study must undergo preoperative examinations as well as upper gastrointestinal endoscopy, and must complete symptom assessment questionnaires both before and after the procedure. Patients will be followed for a total period of 12 weeks after the procedure through telephone contact (calls and/or text messages), e-mails, and periodic follow-up examinations, in order to obtain information regarding the patient's clinical status; this information may also be obtained with the assistance of their relatives or friends to better clarify the data. The confidentiality of all information provided will be guaranteed, as provided by law and mentioned in Resolution 466/12, IV-3-c.

REGARDING CONFIDENTIALITY:

Your data will be kept confidential in accordance with the precepts of the law and regulatory agencies. The results will be published and may be presented at scientific meetings and used for additional research. In accordance with Resolution No. 466 of December 12, 2012, the procedures performed will have their confidentiality and privacy ensured, as well as the protection of the image and the non-stigmatization of the research participants. It will be guaranteed that the information will not be used to the detriment of individuals and/or communities, including in terms of self-esteem, prestige, and/or economic-financial aspects.

ACKNOWLEDGMENT OF THE CONSENT FORM:

I have been sufficiently informed regarding the study “Comparison between local cryoprevention associated with NSAIDs versus NSAIDs alone for reducing the incidence of post-ERCP pancreatitis: a randomized clinical trial.” I have discussed the above information with the Responsible Researcher or the person(s) delegated by him (.....) regarding my decision to participate in this study. The objectives, procedures, potential discomforts and risks, and guarantees have been made clear to me. I voluntarily agree to participate in this study, I sign this consent form, and I receive a copy initialed by the researcher.

_____Date____/____/_____

Signature of the participant / legal representative

_____

Name of the participant / legal representative

_____Date ____/____/_____

Signature of the person responsible for the study