

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

CONSENT FORM

Comparative Study of the Efficacy of Intraoperative Intercostal Cryoanalgesia and Thoracic Epidural Block in the Postoperative Period of Minimally Invasive Pectus Excavatum Repair (MIRPE): a Prospective, Randomized Clinical Trial

Principal Investigator – Dr. Miguel Lia Tedde

Sub-Investigators – Dr. Diego Arley Gomes da Silva; Dr. Paulo Manuel Pêgo-Fernandes

Department/Institute – Thoracic Surgery – Heart Institute (InCor)

You and/or your child are being invited to voluntarily participate in the study entitled “Comparative study of the effectiveness of intraoperative intercostal cryoanalgesia and thoracic epidural block in the postoperative period of minimally invasive repair of pectus excavatum (MIRPE): a prospective, randomized clinical study.”

This research aims to compare two methods of pain treatment that are commonly used after surgery to correct pectus excavatum with placement of metal bars. All participants will undergo the same surgery that was proposed during the outpatient visit (placement of two metal bars under general anesthesia) and will be randomly assigned (by chance) to receive either thoracic epidural block or intraoperative intercostal cryoanalgesia.

The epidural block is the technique most routinely used for pain control in pectus excavatum repair surgery. It involves administering anesthesia in your back and injecting medication into a space near your spinal cord.

Intercostal cryoanalgesia is a technique performed during surgery while you are under anesthesia. It involves applying a probe that cools to very low temperatures for two minutes to each of the nerves located under your ribs that are responsible for the sensation of pain.

Participants will be divided into two groups. These groups will be compared regarding the length of hospital stay after surgery and the amount of pain medication required during hospitalization.

Brief Title: Intraoperative Cryoanalgesia Versus Thoracic Epidural Block in MIRPE (Minimally Invasive Repair of Pectus Excavatum)	Confidential
Consent form version 1.0 – March, 8, 2024	
Principal Investigator: Miguel Lia Tedde Hospital Das Clínicas Da Faculdade De Medicina Da USP	
	<div style="display: flex; justify-content: space-between;"> <div>Participant / Legal Representative Initials</div> <div>Principal Investigator initials</div> </div>

You and/or your child will not have any expenses for the surgery, cryoanalgesia, or thoracic epidural analgesia. Agreeing to participate in this research will not affect the diagnosis and/or treatment, since the surgery to be performed (placement of two metal bars) to correct pectus excavatum in a minimally invasive manner will be the same.

By agreeing to participate, there is a risk of breach of confidentiality of your information. However, we assure you that the data will be processed anonymously (without information that could identify you). There is a possible risk that cryoanalgesia may cause numbness (paresthesia) or chronic pain (neuropathy) in one of the nerves cooled during surgery. Other possible risks during the research are related to the surgical and anesthetic techniques used and may include bleeding, infection, pneumothorax, displacement of the metal bars, among others.

The expected benefit of this research is that patients who undergo intercostal cryoanalgesia may experience more satisfactory pain relief compared to the traditional method (epidural block), according to international literature, after surgery for placement of metal bars in the minimally invasive treatment of pectus excavatum. This research will help determine which of the two evaluated methods (cryoanalgesia or epidural analgesia) is the best form of pain control for patients undergoing the same surgery.

During and after the research, patients will be regularly followed in the Chest Wall Clinic (Pectus Group) for approximately three (3) years, until surgical removal of the metal bars, which is part of the standard treatment of pectus excavatum but is not part of this research. During clinic visits, the surgical correction result and the occurrence of postoperative pain will be evaluated, as routinely performed.

It is important to emphasize that no fees will be charged and there will be no financial compensation for research participants or their legal guardians. There will be no expenses related to the study for the participant or their companion. If any damage occurs as a result of the research, the participant will be entitled to compensation in accordance with the law.

If you decide not to participate in the research, your decision will not affect your treatment in any way. Treatment will proceed normally according to the standard routine for surgical treatment of pectus excavatum. You may withdraw your consent at any time by expressing your decision in writing. This decision will be respected, and your treatment will continue according to the established routine without any prejudice to you, your privacy, or your treatment at HCFMUSP.

Brief Title: Intraoperative Cryoanalgesia Versus Thoracic Epidural Block in MIRPE (Minimally Invasive Repair of Pectus Excavatum)	Confidential
Consent form version 1.0 – March, 8, 2024	
Principal Investigator: Miguel Lia Tedde Hospital Das Clínicas Da Faculdade De Medicina Da USP	
	<div style="display: flex; justify-content: space-between;"> <div>Participant / Legal Representative Initials</div> <div>Principal Investigator initials</div> </div>

After understanding the information provided here, you or your legal representative must express your free and informed consent to participate. This document has been prepared in two identical copies. You or your legal representative must initial all pages and sign in the appropriate place. One signed copy will be given to you.

At any stage of the study, you will have access to the professionals responsible for the research to clarify any doubts. The Principal Investigator is Dr. Miguel Lia Tedde, located at Av. Dr. Eneas de Carvalho Aguiar 44, São Paulo, SP, 05403-000, Telephone: +55 (11) 2661-7999, email: tedde@usp.br. If you have any questions about the ethical aspects of the research, please contact the Research Ethics Committee (CEP) at Rua Ovídio Pires de Campos, 225 – 6th floor – ZIP Code 05403-905, Telephone: +55 (11) 2661-7585 or +55 (11) 2661-1548, Monday to Friday from 7:00 a.m. to 4:00 p.m., or by email: cappesq.adm@hc.fm.usp.br.

I have been sufficiently informed about the study entitled “Comparative study of the effectiveness of intraoperative intercostal cryoanalgesia and thoracic epidural block in the postoperative period of minimally invasive repair of pectus excavatum (MIRPE): a prospective, randomized clinical study.”

I discussed the above information with the Principal Investigator, Sub-Investigators, or their designated representatives regarding my decision to participate in this study. The objectives, procedures, potential discomforts and risks, and guarantees were explained to me. I voluntarily agree to participate in this study, sign this informed consent form, and receive a signed copy.

----- Date ____/____/____

Signature of Participant / Legal Representative

Name of Participant / Legal Representative

----- Date ____/____/____

Signature of Responsible Investigator

Brief Title: Intraoperative Cryoanalgesia Versus Thoracic Epidural Block in MIRPE (Minimally Invasive Repair of Pectus Excavatum)	Confidential	
Consent form version 1.0 – March, 8, 2024		
Principal Investigator: Miguel Lia Tedde Hospital Das Clínicas Da Faculdade De Medicina Da USP		
	Participant / Legal Representative Initials	Principal Investigator initials