**Informed Consent Form for parents or legally acceptable guardians**

| | |
|---|---|
| **Title of the study:** | **Laparoscopic descent with preservation of testicular vessels for intra-abdominal testis: A quasi-experimental study.** |
| **Protocol number:** | **2024/063** |
| **Sponsor:** | Federal Funds |
| **Principal investigator:** | Silvio Carmona Librado |
| **Principal Investigator's phone number available 24 hours a day:** | Cel 55 25 64 06 06 22 |
| **Name and address of the center:** | **National Institute of Pediatrics**<br>Insurgentes Sur 3700-C, Insurgentes Cuicuilco, Alcaldía Coyoacán, 04530 Mexico City, Mexico |
| **Center telephone number:** | 55 1084 0900 Ext. 1487 |
| **Emergency services:** | National Institute of Pediatrics<br>Insurgentes Sur 3700- C, Insurgentes Cuicuilco, Alcaldía Coyoacán, 04530 Mexico City, Mexico<br>55 5068 7256 |
| **Research Ethics Committee:** | Dr. Alberto Olaya Vargas. Research Ethics Committee of the National Institute of Pediatrics. Insurgentes Sur # 3700-C, Col. Insurgentes Cuicuilco, Alcaldía Coyoacán, CP: 04530, Mexico City, Mexico.<br>55 1084 0900 ext. 1581 |

## 1.0 General Information

You are being invited to participate in the present clinical study protocol, because your son has **cryptorchidism**, which is an anomaly in testicular descent, since he did not descend testicle to the **scrotum. I**t is not palpable in the groin (**non-palpable testicle)**, because we consider it is located inside the abdomen (**intra-abdominal testicle**).

Your child is being invited to participate in this study protocol. Before you decide whether you want your child to participate in this study, we would like to explain why this research is being done and what it would involve for you and your child.

The study surgeon or a team member will review this information sheet with you and answer any questions. If there is anything you do not understand, ask the study surgeon. If you wish, you may talk to others about this study. If you agree to have your child participate in this study, you will be asked to sign the informed consent form at the end of this sheet, and you will be given a duplicate.

In addition, if you agree to have your child participate in this study, you can withdraw your consent at any time without explanation. This will not affect the quality of care your child receives.

The principal investigator of this study is **Dr. Silvio Carmona Librado**, a pediatric surgeon attached to the Department of Surgery at the National Institute of Pediatrics, with more than 10 years of experience in various laparoscopic procedures. The researcher is conducting this study to determine if the good results observed in other populations, with this new treatment proposal, are at least as effective and safe as those reported with other surgeons.

## 1.0 General Information

Normally, boys are born with their testicles inside the scrotal sac (**scrotum**). When boys do not have testicles in this location, it is called **cryptorchidism**. Cryptorchidism has repercussions that can result in potential medium—and long-term complications, which may include an increased risk of developing testicular cancer, testicular torsion, inguinal hernia, impaired future fertility, and psychological consequences.

The treatment consists of placing the testicle inside the scrotum and performing surgery. In the case of children like your son who cannot palpate the testicle, at the beginning of the procedure, it is necessary to palpate the testicle under anesthesia

Once fully anesthetized, if the testicle cannot be palpated (**non-palpable testicle**), it is most likely because it is inside the abdomen. Laparoscopic surgery is then performed.

**Laparoscopic surgery** consists of introducing a video system through the umbilicus (a 5mm camera) to find the testicle that we suspect is inside the abdomen. Once located, the surgeon evaluates the shape and size of the testicle and determines if it is a candidate for descent into the scrotum.

A patient who has the testicle inside the abdomen traditionally requires 2 operations to place the testicle in the scrotal pouch.

The traditional technique (**Fowler-Stephens technique**) is performed in 2 surgeries. In the first

surgery, the main blood supply of the testicle is cut (**testicular vein and artery**) since these vessels are very short, which prevents the testicle from descending to the scrotum in a single surgery. In the following 6 months, the testicle develops blood circulation through another structure that communicates with the testicle called the vas **deferens**. The vas deferens in adulthood will carry the sperm, and this duct has an artery that will help supply blood to the testicle. This artery in the following months has to grow enough, so that in the second surgery, which is performed 6 months after the first surgery, it will continue to provide blood to the testicle and allow it to descend to the scrotum, without the limitation of the length of the testicular vessels that prevented its descent.

Unfortunately, this technique (**Fowler—Stephens**) involves cutting the testicular vessels, which can cause the testicle not to get enough blood through the vas deferens. The descended testicle then starts to become smaller than its initial size. This is known as **testicular atrophy and affects** future fertility.

## 2.0 Purpose of the study

This study aims to analyze 2 techniques that do not cut the main blood supply of the testicle (**preservation of testicular vessels**) as the traditional technique does and allow to descend the testicle with less risk of testicular atrophy compared to the traditional technique that involves cutting the testicular artery and vein (**Fowler - Stephens**). Techniques that do not cut/preserve the testicular vessels are called **Shehata** and **VILO**, which are based on the same principle but depend on the length of the main blood supply of the testicle.

In some cases, boys may have a testicle of good size and shape, a long testicular artery and vein, and a long enough vas deferens to allow it to be descended into the scrotum in a single surgery. If so, the testicle could be descended with only one surgery, a surgical technique known as **VILO**, but not all patients can do this.

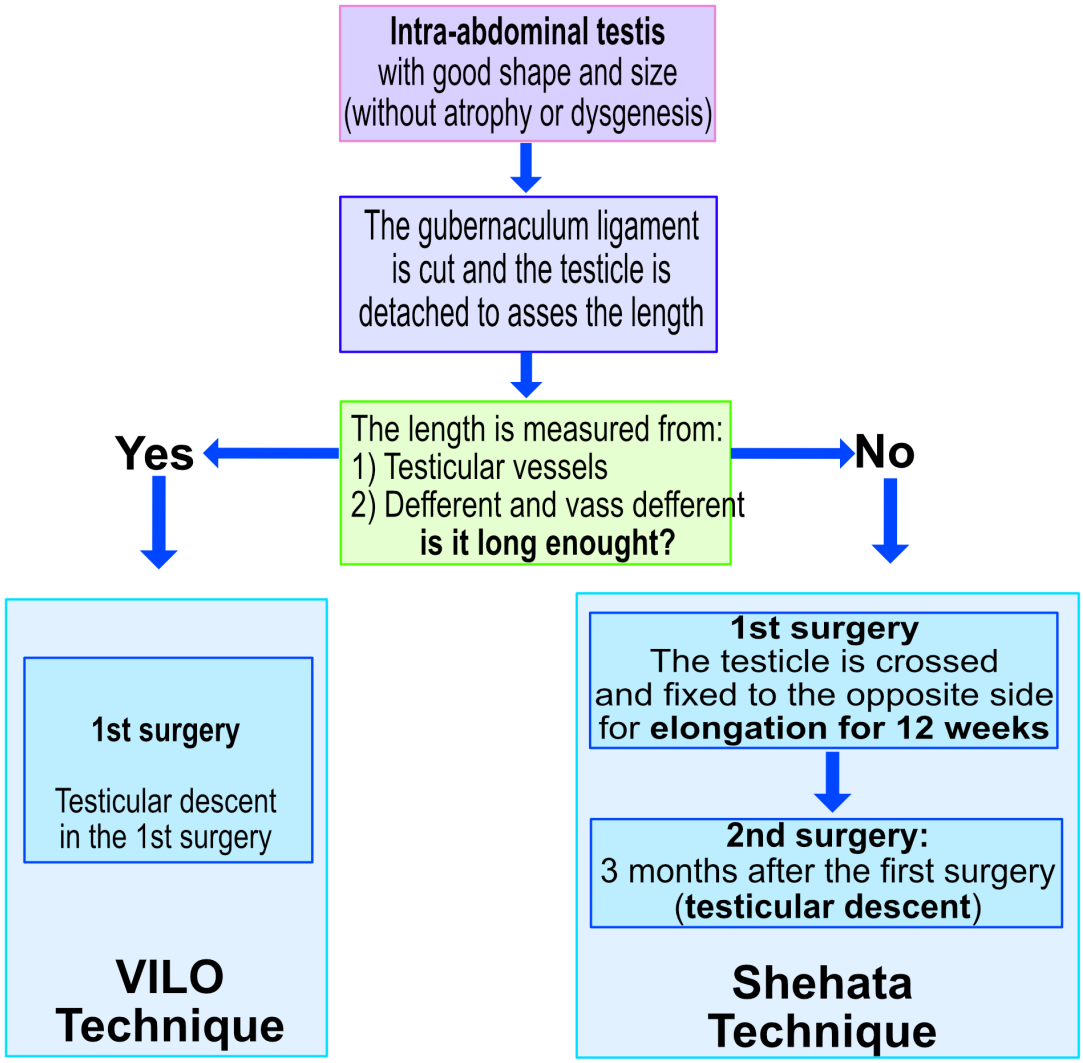
The technique called **Shehata** has been described recently. It is used to descend an intra-abdominal testicle with short testicular vessels, limiting the descent in a single surgery. In these cases, the descent is performed in 2 surgeries. In the first surgery the testicle is detached, mobilized and fixed inside the patient's abdomen to the contralateral side, with the intention that with the patient's movements and the movements of the intestine, "stretch" (elongate) the testicular artery and vein as well as the vas deferens and its artery, in a period of 3 months.

After this, the patient is again admitted to the operating room to perform the second laparoscopic surgery. In case the affected testicle is already long enough, it can be descended to the scrotum, preserving its main arterial and venous irrigation. Thus, we consider that, with this technique, the possibility of testicular atrophy is also lower.

This protocol will only include boys who will undergo one of the two **testicular vessel sparing** techniques (Shehata or VILO); that is to say, if your son during the laparoscopy it is documented that the testicles are inside the abdomen, and that they have an ideal shape and size to be descended, in the first instance, the medical team will try to descend them with the VILO technique, but in case it is not possible, the doctors will proceed to perform the Shehata technique, which includes at least one more surgery.

The following diagram shows the possible scenarios if you agree to have your child participate in this protocol.

# Proposal for laparoscopic descent with preservation of testicular vessels for intra-abdominal testis




3.0 Study design and treatment.

Twenty-eight children with intra-abdominal testis will be included in the study, which implies at least 1 or 2 surgeries within a minimum of 3 months between surgeries.

Your child must attend the procedures requested by the study physicians, in addition to taking care of his wounds, following the diet recommended for the patient, ensuring daily bathing and ambulation at home, and monitoring and reporting alarm data such as intense pain, fever, and

refusal to take the oral route.

It is important to consider that your child may remain hospitalized or return to the emergency room to be evaluated and receive medical treatment if necessary.

Patients operated with one technique or the other will be seen and followed up in an outpatient clinic to evaluate the surgery's results. The size of the testicle and its position will be evaluated to document that these techniques produce better results.

**Postoperative management:**

Once the patient has undergone surgery, he/she goes to recovery. In recovery, they receive similar management to that given to other patients for other surgeries who are routinely discharged home after their surgery. Once the child is conscious/awake, they will be started on oral clear liquids. After the patient is tolerating the oral route and ambulating without extreme pain, he/she can be discharged home.

If the doctors consider that after the surgery it is convenient to remain hospitalized at least one night, then the patient will go to the hospitalization area on the 2nd floor, where they will receive the management and surveillance that is usually given to these patients, which consists of restarting the oral route the next day, as long as the doctor considers it appropriate, continuing with medications for postoperative pain control. After a medical evaluation, the patient will be discharged the following day, with the same management as the rest of the patients operated on for cryptorchidism.

### 4.0 Study Activities and Time Commitment

Your son's participation in the study will last for at least 6 months after the surgery in which the testicle was successfully placed in the scrotum. Regardless of the study protocol, your son will continue to be reviewed annually on a normal outpatient basis.

After discharge from the hospital, patients should attend their first postoperative appointment after 7-10 days in the minimally invasive surgery outpatient clinic (2nd floor). In this first appointment, the patient's wounds will be reviewed, whether the patient has been operated with the VILO technique or the Shehata technique. Any doubts will be clarified, and a new request will be given to the parents for an ultrasound two and a half months prior to their second surgery in the case of patients with the Shehata technique.

With this second ultrasound, we will evaluate the size and position of both testicles. You should go to the second post-surgical consultation between the 10th and 11th week post-surgery (2 and a half months) with the ultrasound result. In this consultation, the patient's wounds and the result of the second ultrasound will be reviewed again. For those patients whose testicles have been descended in only one surgery (VILO), the characteristics of both testicles, such as their size and position, will be reviewed.

If your child did NOT HAVE sufficient length and the surgeon chose to do the Shehata technique,

you will be given the documentation to schedule his 2nd surgery, which will be performed at least 12 weeks after the first surgery (3 months) and must have new labs of blood biometry and coagulation times, as a minimum.

In the second surgery of the Shehata technique, it is assessed that the testicle has elongated sufficiently and retains a good size to descend. However, there have been cases in which, during this 12-week period, the testicle has inadvertently become detached from its contralateral fixation, so that, during the second laparoscopic surgery, if the detached testicle is found, without having achieved sufficient elongation/stretching, it will be necessary to fix it again, to subject it to a new 12-week period of intra-abdominal elongation.

If your child has undergone the last correction surgery with the Shehata technique, you should also visit your child within 7-10 days after surgery and then again with another ultrasound at 6 months.

Whether your son has had the VILO technique or the Shehata technique, the final results of the surgeries will be assessed 6 months after placement of the testicle in the scrotum, with an ultrasound and medical review.

**Selection:**

At screening, the study doctors will ask you some questions about your child's personal information and medical history. You will also be asked to have your son complete some procedures and tests, including a physical examination, laboratory studies (blood biometry and clotting times), imaging studies such as inguinoabdominal testicular ultrasound, and nutritional assessment. If your son does not palpate his testicles, he will be scheduled to be taken to the operating room for palpation under anesthesia. If, despite being under anesthesia, the testicle cannot be palpated, a diagnostic laparoscopy will be performed at that time to look for it. If the testicle is found in the abdomen with good shape and size, the length of the vessels will be measured to determine if it can be descended in surgery or if your son will require two surgeries to descend the testicle. Information on what tests will be done and when they will be done is shown in the following table:

| Evaluation program for protocol participants:<br>**Laparoscopic management of intra-abdominal testicles, with the VILO technique.** | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Selection** | **Treatment** | | | **Follow-up** | | | | | | | | |
| Day | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2-3 d | 7-10 d. | 3 months | 6 m | 12m |
| | 1<br>CE | Instruction and preoperative assessment | Surgery laparoscopic | Recovery | Medical visit recovering | Exit with written instructions | Hospitalization | Medical visit | Egress | Consultation | Consultation and USG | Consultation and USG | Consultation and USG |
| Vital signs | x | x | x | x | x | | x | x | | x | x | x | x |
| Weight and size | x | x | x | | | | | | | x | x | x | x |
| Medical history | x | x | | | | | | | | | | | |
| Physical examination | x | x | x | x | x | | x | x | | x | x | x | x |
| Demographic characteristics | x | x | | | | | x | | | | | | |
| Testicular/inguinoabdominal ultrasound | x | | | | | | | | | | x | x | x |
| Signature of informed consent | x | x | | | | | | | | | | | |
| Preoperative studies | x | x | | | | | | | | | | | |
| Wound revision | x | | | x | x | | x | x | | x | x | x | x |
| | | | | | | | | | | | | | |

| Evaluation program for protocol participants:<br>**Laparoscopic management for intra-abdominal testis, with the Shehata technique.** | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Selection** | **Treatment** | | | **Follow-up** | | | | | | | **Treatment** | **Follow-up** | | | |
| Day | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 2 | 2-3 d | 7-10 d. | 2.5m | 3 months | 7-10 d | 3m | 6m | 12m |
| | 1 CE | Instruction and preoperative assessment | Surgery laparoscopic | Recovery | Medical visit recovering | Exit with written instructions | Hospitalization | Medical visit | Egress | Consultation | Consultation and USG | 2nd Surgery laparoscopic | Consultation | Consultation | Consultation and USG | Consultation and USG |
| Vital signs | x | x | x | x | x | | x | x | | x | x | x | x | x | X | x |
| Weight and size | x | x | x | | | | | | | x | x | x | x | x | X | x |
| Medical history | x | x | | | | | | | | | | | | | | |
| Physical examination | x | x | x | x | x | | x | x | | x | x | x | x | x | X | x |
| Demographic characteristics | x | x | | | | | x | | | | | | | | | |
| Testicular/inguinoabdominal ultrasound | x | | | | | | | | | | x | | | | x | x |
| Signed informed consent form | x | x | | | | | | | | | | | | | | |
| Preoperative studies | x | x | | | | | | | | | | | | | | |
| Wound revision | x | | | x | x | | x | x | | x | x | x | x | x | x | x |
| | | | | | | | | | | | | | | | | 12m |

| Procedure | What is this? |
|---|---|
| Measurements of vital signs. | Your child's blood pressure, heart rate, breathing rate and temperature will be measured. |
| Demographic characteristics/medical history/concomitant medications | The study doctor will collect your child's personal information, including age, gender, religion.<br>At each study visit, you will be asked if your child has had any illnesses or problems related to his or her surgery that caused him or her to seek medical or health care services, including surgical procedures, and about all medications (including over-the-counter medications) that your child has received in the past month or is currently receiving. |
| Physical examination, weight and height | A complete physical examination will be performed, with weight and height measurements.<br>Weight and height measurements are taken at each visit. |
| Testicular Ultrasound | You will receive the request for a testicular ultrasound, where both testicles will be analyzed, the healthy one and the affected one, with special interest in the measurement of the testicle, the inguinal canal, its blood supply, and the determination of the volume and its anatomical position. You must schedule and come in time and form to perform the ultrasound in the X-ray department, located on the 1st floor. |
| Preoperative studies | You will receive a request for labs, which must be taken prior to the anesthesia assessment. You must go to schedule the taking of these and go with your child for the taking of these. These are: Blood Biometry, Coagulation Times. In case the doctor considers it necessary, he/she may request any other laboratory in addition to these. |
| Preoperative instructions and assessment | You must come with the pertinent documentation and requirements as any other patient, to request the pre-anesthetic assessment appointment.<br>You should go to preoperative assessment, where the Anesthesiology service will evaluate your child, making an interrogation of their history, in addition to physical examination and preoperative studies will be reviewed. The anesthesiologist will determine if he/she is fit to go to the operating room. If no, an appointment for reevaluation will be made. |
| Surgery | In case it is corroborated that the testicle is inside the abdomen, your son will be included in this study protocol. During the surgery the doctors will determine if your son is a candidate for descent in one surgery (VILO), or if he will require at least 2 surgeries (Shehata) based on the length of the testicular vessels. |
| Delivery of medical instructions | In the case of patients, the medical staff considers pertinent their discharge after surgery, they will receive a series of written instructions of all the care that you should give to your child. Instructions for: 1) type of diet, the duration of the diet, 2) analgesics for pain, dosage, frequency and duration of the same, 3) instructions for management and wound healing, 4) general measures such as early mobilization, 5) alarm data, for which they should bring their children to the emergency room, and 6) the date of consultation for follow-up. |

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| | |
| Wound revision | At each medical visit or outpatient visit, the surgical wounds will be checked. The patient will be checked for infection, dehiscence (opening), changes in color, as well as the degree of healing. |
| Complications | Any adverse effects related to the surgery, medical care, or medications administered to your child throughout this process will be recorded. |

All biological samples obtained during the study and the data obtained from those samples will only be handled for the reasons indicated in the study protocol and in this informed consent form.

The results of these tests with your child's leftover specimens are not intended to provide you with any clinical information. The results are for preoperative assessment and for the purposes of this research. The results of these tests will not be shared with you, any insurance company, your family, or any other physician who treats your child outside of the INP now or who may treat your child in the future. Your child's personal information will be kept confidential to the extent applicable by laws and regulations.

### 1.0 Potential required discomfort and/or hazards

The safety of these surgeries has already been evaluated in other hospitals in other countries. Likewise, as previously mentioned, the institute has experience in managing patients with intra-abdominal cryptorchidism managed laparoscopically with other techniques.

The possible complications of any patient operated by diagnostic laparoscopy + Orchidopexy in one (VILO) or two surgical times (Shehata), are: Wound infections of the abdomen or scrotum, intra-abdominal bleeding, post-operative paralytic ileus, intestinal injury, bladder injury, inguinal hernia, umbilical hernia, testicular atrophy, intra-abdominal fall of the testicular fixation (1st time of Shehata), this last one, will require new fixation with its respective elongation period, to obtain better results. Also, the complications of these two techniques are the presence of testicular atrophy and the testicles not being able to descend correctly into the scrotum.

These are presented with any management technique for patients with intra-abdominal cryptorchidism, so at the National Institute of Pediatrics, we intend to update our management protocol, for which we are inviting you to participate.

It is possible that your son may present with the formation of an intra-abdominal collection, secondary to the manipulation and dissection to release the testicle, which in many cases requires only medical surveillance and treatment.

It is possible that your son may present with the formation of an intra-abdominal collection, secondary to the manipulation and dissection to release the testicle, which in many cases requires only medical surveillance and treatment.

In some cases, the presence of postoperative paralytic ileus has been reported, manifested by abdominal distension, refusal of the oral route, vomiting, consequence of lack of effective movement of the intestines, which will require your child to fast and walk a lot after surgery, in addition to medical surveillance and treatment in most cases.

It is possible that your son, like all operated patients, may present pain in the wounds, abdomen or scrotum, so all patients are discharged with medical management with analgesics to reduce or avoid this discomfort, expected in any operated patient. In other cases, your son could present infection of the surgical wounds, so you should inform and seek medical attention and inform the medical staff of the study protocol to receive the required care promptly.

Your child will be monitored for any of these possible eventualities. In the event that your child requires hospitalization, parents will be informed, and medical treatment or even surgical treatment will be provided if required.

If your child receives any additional treatment during the study, you should inform the study physician so that the treatment can be recorded.

## 2.0 Potential benefits

It is expected that your son will benefit from a management protocol based only on testicular vessel preserving techniques, thus preserving the main irrigation of the testicle, so we consider that these techniques offer better results than the traditional technique that cuts the main irrigation of the testicle (testicular vessels), With the advantage of being operated in a standardized laparoscopic way, which in most cases will allow the patient to be discharged on the same day of surgery, avoiding risks associated with hospitalization, such as longer exposure to intrahospital germs.

The information obtained from the study will help develop better medical-surgical treatments for children with intra-abdominal testis, with better medium—and long-term results.

## 3.0 Responsibilities

As participants in this study, you and your child have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You should make sure that your child does not participate in any other clinical trials until your participation in this study is completed. Participating in another study before the end of this study may affect the results of this study. Your child's participation in this clinical trial will end immediately if you decide to participate in another clinical trial.
- You and your child must attend all required visits to this study center (National Institute of Pediatrics).
- Your child should take the medications as directed.
- You should inform the study physician of any unusual symptoms and go to the emergency room for evaluation in case of fever, abdominal pain, abdominal distention, persistent

vomiting, or wound discharge.

- You should inform the physician or study staff if you decide that you no longer want your child to participate in the study, so that a plan can be made for your child's continuity of care.

### 4.0 Compensation/cost participation

You will not be paid for your child's participation in the study.

Your child's participation in this protocol is free of charge and the National Institute of Pediatrics funds the costs of surgical care. As mentioned, participation in this study contributes to developing new medical/surgical treatments for the pediatric population.

### 5.0 Major Medical Insurance.

Before participating, you should consider whether this will affect your insurance and seek advice if necessary.

No financial compensation will be available for such things as lost wages, disability or inconvenience due to any damages related to the investigation. By signing this form, you do not waive any legal right to seek additional compensation through a court of law.

### 6.0 Voluntary participation and withdrawal

Your child's participation in this clinical trial is voluntary. You may choose not to allow your child to participate in this study, either at the start or at any time during the study. Your decision will not adversely affect your child's present or future medical care. Nor will it involve any penalty or loss of benefits to which your child is otherwise entitled. To ensure your child's safety, you will be asked to have your child undergo some final evaluations. If you wish to withdraw your child from the study, contact the doctor or staff.

***You may also revoke authorization for using or disclosing your child's personal health information. If you choose to withdraw your authorization, you must notify the study doctor in writing.***

The study doctor may stop your child's participation in this study without your consent if you do not follow the doctor's instructions. In addition, your child may be withdrawn from the study if, in the opinion of the study doctor, the proposed management protocol is not the best option for your child or for reasons deemed appropriate by the study doctor. Your child's participation may also be terminated if a supervising government agency decides to stop the study. If your child is removed from the study, you will be asked to undergo appropriate medical testing and follow-up to assess your child's health and safety.

## 7.0 Alternative treatments

If you do not want your son to participate in this study, your son will continue to be treated by his regular physician/surgeon, and his care will not be affected in any way. The study doctor will inform you what treatments are available for your son to resolve the cryptorchidism with non-palpable testis with possible intra-abdominal testis that he has. The study doctor will help explain open and laparoscopic treatment and your usual medical management and surveillance. Each surgical approach has risks and benefits, which your doctor will help you consider.

## 8.0 Who to contact

### **8.1** To ask questions or to report a possible harm or reaction related to the investigation

If you have any questions about your child's participation in this study, or if you believe your child has experienced any research-related harm or reaction to study drug, you should contact:

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| Name of contact in case of emergency: | Dr. Silvio Carmona Librado |
| Phone: | 55 25 64 06 22 extension: 1487 |
| Number in service: 24 a day: | Cellular 55 25 64 06 22 |

Alternate Name and Phone Number: Dr. XXXXXXXX
55 XXXXXX

### **8.2** To report a breach of confidential information

If you feel your child's confidential information has been breached, contact the study physician (see contact details on page 1).

### **8.3** To ask questions about your rights as a research participant

This clinical trial has been reviewed and approved by a Research Ethics Committee and a Research Committee. These committees are groups of people in the community responsible for reviewing and approving the conduct of proposed research. If you have any questions about your child's rights as a research, you may contact:

The Research Ethics Committee (REC):

| | |
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| **Name of the IRB:** | Research Ethics Committee of the Institute National Pediatrics |
| **Name of IRB contact:** | Dr. Alberto Olaya Vargas |
| **Address:** | Insurgentes Sur number 3700- C, Insurgentes Cuicuilco, Alcaldía Coyoacán, 04530, Mexico City, Mexico |
| **Phone:** | 55 1084 0900 extension: 1581 |

## 9.0 Recording the clinical study

A description of this clinical trial will be available at http://www.ClinicalTrials.gov. These websites will not include information that could identify your child. Most websites will include a summary of the results after the study is completed. You may search these websites at any time.

A description of this clinical trial will also be available at: http://siipris03.cofepris.gob.mx/Resoluciones/Consultas/ConWebRegEnsayosClinicos.asp, in the National Clinical Trials Registry (Registro Nacional de Ensayos Clínicos, RNEC), as required by Mexican law.

## 10.0 Confidentiality and data protection

The principal investigator is responsible for all personal data collected about your child during the study and for ensuring that all persons working on the study comply with all data protection requirements for collecting, using, and processing of personal data collected in this study. This responsibility rests with you as the data.

The study site, as the entity that will collect and process your child's personal data for the purposes of the study, will also be a data controller regarding your child's personal data.

The principal investigator is responsible for deciding what personal data should be collected during the study and how the data will be used. The study physicians will be responsible for collecting personal data, as necessary, for your child to participate in the study. Along with medical data (including laboratory specimen data), other information collected may include your gender, age (days and months), ethnicity, body weight and height, and nutritional status. Personal data will be documented in coded form (using only your child's specific study participant number, not your child's name). Only the physician and study staff will be able to identify your child from the code

Your child's personal data is collected, used and disclosed in the study based on legitimate interests of the principal investigator for the conduct of scientific research or, in certain circumstances, based on a legal obligation, for example, to allow the investigator to test the results of the study or to report any adverse effects your child may experience with the treatment modality assigned in the study.

Authorized representatives to whom personal data is disclosed are bound by their duty of confidentiality to you and your child and professional medical rules in this regard. They are authorized to transmit participants' personal data only in coded form and are not allowed to make photocopies or written duplicates of your child's medical records.

Your child's personal information will be stored until the end of the study and for a period required by law. The researcher will take all reasonable steps to protect your child's privacy as required by law, including informing you what safeguards are in place to secure your child's personal information. Some ways in which your child's personal information is kept secure include requiring study sites to have appropriate measures in place for the security of your child's personal information, removing certain direct identifiers from your child's personal information or encrypting it with a key so that your child cannot be identified, and collecting only the personal information that is necessary. You can request this information on preventive measures from the study doctor.

The Central Laboratory of the National Institute of Pediatrics will analyze blood samples, which correspond to the studies usually requested in all patients with cryptorchidism with a non-palpable testicle and possible intra-abdominal testicle.

You may refuse to sign the consent regarding collecting and processing personal data. However, this will prevent your child from participating in the study. You may also choose at any time to withdraw your consent to participate or to the processing of personal data after the start of the study. The data collected cannot be deleted because of the legal requirement to store all study data and because it is necessary to preserve the integrity of the research.

**You have certain rights** to obtain access to your child's personal information collected and stored and to request that any inaccuracies be corrected. You may request that the use of your child's personal data be limited or that your child's personal data be deleted; , these rights may be limited to protect the integrity of the study. You may exercise these rights by submitting a written request to the researcher. You may do this by a request submitted through the study physician, He/she will forward the request to the investigator. If you decide that your child will no longer participate in the study, no additional personal data will be collected. All personal data collected up to the time of your withdrawal from the study must be retained and used, as they are part of the study data

Your child's personal data will be kept confidential if the study results are published.

Your child's data will be electronically recorded, processed, encrypted, and transmitted over the Internet, via a secure connection, to the rest of the research team for this study protocol.

Third parties involved who are not authorized study personnel at the study site will not be able to read your child's data.

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|---|---|
| **Title of the study:** | **Laparoscopic management for intra-abdominal testis: a quasi-experimental study.** |
| **Protocol number:** | 2024/063 |
| **Sponsor:** | Federal Funds |

**By signing this form, I voluntarily consent to my child's participation in the medical/surgical study and agree to the following:**

| | Place a brand |
|---|---|
| • I have read the description of the clinical trial, and it has been explained to me in words and terms I understand; I have had the opportunity to ask questions, and all questions have been answered to my satisfaction. I understand that my child's participation is voluntary. I know enough about the purpose, methods, risks, and benefits of the clinical trial to decide whether my child will participate in it. | |
| • I voluntarily agree to have my child participate in this study. | |
| • The study doctor will inform me of any new findings, arising during the course of this study, that would reasonably be expected to affect my willingness to have my child continue to participate. In such cases, it is possible to to ask me to sign an updated consent form. | |
| • I authorize the release of my child's medical records related to the study to the principal investigator. | |
| • I understand that I will be provided with a signed duplicate of this informed consent form. | |
| • By signing this consent form, I acknowledge that I have read this information, that I have had the opportunity to ask as many questions as I wanted, and that I have received satisfactory answers to my questions. I understand that I have not given up any of the legal rights my child has as a participant in a clinical study. | |
| • ***I also authorize the use and disclosure of my child's personal health information. My child will not be able to participate in this clinical trial without this authorization. If I refuse to give my authorization, my child's care will not be able to my child's medical care will not be affected.*** | |
| • By signing this form, I consent to the collection, use and storage of my child's personal information and medical data in databases, and its disclosure, as described in Section 14 of this form, under an obligation of confidentiality. I understand that my right of access and correction is preserved and will be made possible through the researcher as data controller. | |

I know that, at any time and without providing any reason, I can withdraw my consent and stop my child's participation in the study. This will not affect my child's medical/surgical treatment or care.

I will receive a signed duplicate of this Information Sheet and Informed Consent Form for parents/legally authorized representatives to keep.

## Signatures

| | |
|---|---|
| **Participant's name:** _____ | |
| **Mother/legally acceptable representative** | |
| | Name, printed |
| Signature | Date, in block letters dd/mmm/yyyyy |
| **Parent/legally acceptable representative** | |
| | Name, printed |
| Signature | Date, in block letters dd/mmm/yyyyy |

| | |
|---|---|
| **Researcher obtaining consent** | |
| | Name, printed |
| Signature | Date, in block letters dd/mmm/yyyyy |

| | |
|---|---|
| **Witness No. 1** | |
| | Name, printed |
| Signature | Date, in block letters<br>dd/mmm/yyyyy |
| Address | |
| Relationship with the subject | |
| **Witness No. 2** | |
| | Name, printed |
| Signature | Date, in block letters<br>dd/mmm/yyyyy |
| Address | |
| Relationship with the subject | |