The AMPER Study: Amniotic Membrane for the Prevention of mesh Exposure in vaginal Reconstructive surgery

Informed Consent Form (ICF)

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Informed Consent Form (ICF)

APPLICATION OF AMNIOTIC MEMBRANE FOR THE PREVENTION OF MESH EXPOSURE IN VAGINAL PELVIC ORGAN PROLAPSE AND STRESS URINARY INCONTINENCE SURGERY (AMPER STUDY)

You are being invited to participate in a research study because you have been diagnosed with pelvic organ prolapse and/or stress urinary incontinence that requires surgical repair. We are a group of researchers working on these common conditions affecting women.

Your participation in this study is entirely voluntary. You may choose whether or not to participate.

We will provide you with information about the study and ask for your participation. You do not have to decide today. Before making a decision, you may discuss this study with anyone you trust and feel comfortable with.

Introduction

Polypropylene mesh used through the vaginal route for the treatment of prolapse is a synthetic surgical device designed to correct apical prolapse—either of the vaginal vault or the cervix—using minimally invasive suspension techniques. It is also used in procedures to treat stress urinary incontinence. One of the most frequent complications associated with its use is mesh exposure, which occurs in approximately 10% of cases.

In this context, the use of human amniotic membrane may represent a useful alternative to prevent this complication. The amniotic membrane is a natural tissue obtained from the inner layer of the placenta, which surrounds and protects the baby during pregnancy.

This tissue has several beneficial properties:

- Reduces inflammation
- Limits excessive blood vessel formation (anti-angiogenic effect)
- Has antimicrobial properties
- Prevents dense or hypertrophic scar formation
- Promotes faster tissue healing and regeneration

For these reasons, it has been successfully used in different types of surgery, including gynecological, urological, and ophthalmological procedures. Our objective is to evaluate whether placing amniotic membrane together with the mesh during vaginal surgery may improve tissue tolerance and reduce complications.

The Study

This is a randomized, single-blind clinical study.

If you agree to participate and meet all eligibility criteria, you will be assigned to one of two groups:

- a group in which amniotic membrane will be used, or
- a group in which it will not be used.

Neither you nor your surgeon will be able to choose the group assignment. Allocation will be random (similar to flipping a coin). The study is called “single-blind” because neither you nor the person who evaluates you later will know whether amniotic membrane was used.

We need to compare the standard surgical technique with the addition of amniotic membrane because we do not yet know whether it reduces the frequency of mesh exposure.

The results will be recorded in our study database but will not be analyzed until the study is completed. This helps avoid bias and ensures objective results. We will then compare which technique is more effective.

Study Procedures

You will be evaluated and operated on using the usual procedures and standard surgical technique indicated for your type of pelvic organ prolapse and/or stress urinary incontinence.

For patients assigned to the intervention group, the materials routinely used during surgery will be covered with amniotic membrane.

The amniotic membrane used in this study will be provided by AMNIOS BMA, a non-profit organization that functions as a human amniotic membrane bank in Argentina. It is authorized by INCUCAI and ANMAT.

Donated placentas are processed by lyophilization and gamma irradiation sterilization, producing sterile amniotic membrane patches suitable for surgical use.

The total study duration will be 52 weeks. After surgery, you will be asked to return for follow-up visits at weeks 1, 4 (1 month), 12 (3 months), 24 (6 months), 36 (9 months), and 52 (12 months). These visits are also part of the routine postoperative follow-up for all patients.

At these visits, a standard gynecological examination will be performed, and you will be asked to complete a short questionnaire.

Risks

There are no known risks specifically associated with the use of amniotic membrane.
The risks related to participation in this study are those inherent to the surgical procedure itself and are described in the surgical consent form.

Benefits

You may not receive any direct benefit from participating in this study. However, your participation may help us answer the research question and may benefit other women in the future.

Participant Responsibilities

If you choose to participate, you agree to:

- follow the investigator's instructions,
- allow access to your medical records,
- inform the research team of any new problems or complications related to the surgery.

Alternatives to Participation

If you decide not to participate, you will still receive the standard treatment for your condition according to this hospital's protocols.

Costs

Participation in this study will not result in any additional cost to you.
The amniotic membrane will be provided free of charge by AMNIOS BMA.
AMNIOS BMA does not provide financial support for this study.

Compensation

You will not be paid for participating in this study.

Investigator Compensation

Investigators do not receive additional payment for conducting this study.

Medical Care

No harms specifically related to the use of amniotic membrane are known.
However, you will receive medical care and treatment for any usual surgical complications.

Voluntary Participation and Withdrawal

By signing this consent form, you do not waive any of your legal rights under Argentine law.

Your participation is completely voluntary. You are not required to participate to receive medical care. If you decide not to participate, your treatment and your relationship with your physician will not be affected.

If you agree to participate, you may withdraw your consent at any time without losing any rights or affecting the quality of your medical care.

Confidentiality

All personal information collected during this study will be kept strictly confidential in accordance with Argentine data protection laws.

You will be identified by a code number and your initials. Your identity will not appear in scientific reports or publications.

Under Argentine Law 25.326, you have the right to access your personal data free of charge at least every six months and to request corrections if needed. To preserve scientific integrity, some study information may not be available until the study is completed.

Study Contact Information

Please take the time you need before deciding whether to participate. We will be happy to answer any questions.

If you have any questions about this study, please contact the study investigators: Daquino, MD; Pierandrei, MD; Lee, MD; Costanzo, MD; Gelaf, MD; Cahaud, MD; or Sänger, MD. Email: uroginpenna@gmail.com

This study has been approved by the Ethics Committee of Hospital J.M. Penna and the Central Ethics Committee of Buenos Aires.

Please keep these information sheets for your records.

Participant Rights Contact

This study has been reviewed and approved by the Hospital Penna Research Ethics Committee (Registration Code: 18099) in accordance with institutional and ethical guidelines.

If you have questions about your rights as a participant, you may contact to this mail: ceipenna@yahoo.com.ar

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Consent Form

I agree to participate in this study. I have had the opportunity to ask questions and feel they have been answered satisfactorily. I understand that participation is voluntary and that I may withdraw at any time without losing any rights.

I understand that if I wish to withdraw, I may contact Dr. Ileana Sänger (Ilesaenger@gmail.com).

I have read this consent form. My questions have been answered, and all parts of the study have been explained to me. I have received a copy of this form.

Participant signature: _____

ID number: _____

Printed name: _____

Investigator signature: _____

Witness signature (if required): _____

I certify that I observed the informed consent process. The prospective participant read the consent form, was given adequate opportunity to ask questions, appeared to understand the information provided, and voluntarily signed the form to participate in the study.