INFORMED CONSENT FORM

Official Title:

Single-Layer Versus Double-Layer Uterine Closure After Primary Cesarean Section: Impact on Residual Myometrial Thickness and Cesarean Scar Defect Formation — A Prospective Randomized Controlled Trial

NCT Number: Pending

Protocol ID: 31/26

Document Date: April 23, 2026

Important Note:

This Informed Consent Form was approved by the Ethics Committee of the Faculty of Medicine of Sfax prior to enrollment of the first participant. A signed copy of this form is provided to each participant for personal records.

Institution: Department of Obstetrics and Gynecology

Hedi Chaker University Hospital Sfax, Tunisia

Principal Investigator: Dr. Larbi Nizar, MD

Department of Obstetrics and Gynecology

Hedi Chaker University Hospital, Sfax, Tunisia

Email: dr.larbinizar.obgyn@gmail.com

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Supervisors: Professor Derbel Mohamed

Professor Khanfir Fatma

Department of Obstetrics and Gynecology

Hedi Chaker University Hospital, Sfax, Tunisia

Ethics Committee Approval: Ethics Committee of the Faculty of Medicine of Sfax, Tunisia

Approval Number: 31/26

INFORMED CONSENT FORM (ICF)

Study Title:
Single-Layer Versus Double-Layer Uterine Closure (Hysterorrhaphy) After Primary Cesarean Section: Impact on Residual Myometrial Thickness and Cesarean Scar Defect Formation

Principal Investigator: [Larbi Nizar, MD]
Institution: Department of Obstetrics and Gynecology, CHU Hédi Chaker, Sfax, Tunisia
Contact: [+21693726918] | [dr.larbinizar.obgyn@gmail.com]
Ethics Approval Number: [31/26]
ClinicalTrials.gov Identifier: [To be assigned]
ICF Version: 2.0 | **Date:** January 2025

SECTION A: INTRODUCTION

You are being invited to participate in a medical research study conducted at the Department of Obstetrics and Gynecology of CHU Hédi Chaker, Sfax. Before you decide whether to participate, it is essential that you fully understand what the study involves, why it is being conducted, and what your participation would mean for you.

Please read this document carefully and take as much time as you need. You are strongly encouraged to ask any questions, whether before, during, or after

reading this document. You may also discuss your participation with your family or your personal physician.

Your participation in this study is entirely voluntary. If you decide not to participate, or if you choose to withdraw at any time, your medical care will not be affected in any way whatsoever.

SECTION B: PURPOSE OF THE STUDY

You are currently pregnant and are scheduled to have a **cesarean section (C-section)**. During a cesarean section, the surgeon makes an incision (cut) in the uterus to deliver your baby. After delivery of your baby and placenta, the surgeon must stitch this incision closed. There are currently **two accepted techniques** for doing this:

Technique 1 — Single-Layer Closure:
The uterine incision is closed with a **single row of stitches** passing through the full thickness of the uterine wall in one pass.

Technique 2 — Double-Layer Closure:
The uterine incision is closed with **two successive rows of stitches** — the first row closes the deep part of the uterine wall, and the second row reinforces the first.

Both techniques are safe, accepted, and routinely used in hospitals worldwide. However, medical evidence has not yet clearly established which technique leads to better uterine scar healing.

After a cesarean section, the uterine scar does not always heal perfectly. Incomplete healing can result in what is called a **"scar defect"** (also known as a uterine niche or isthmocele) — a thinned or irregular area of the uterine wall at the scar site. This defect can sometimes cause:

- **Unusual vaginal bleeding or spotting** between periods
- **Pelvic pain** or painful periods
- In rare and severe cases, **complications in future pregnancies** if the scar becomes too thin

The purpose of this study is to determine which stitching technique results in:

1. A **thicker and better-healed uterine scar** (measured by internal vaginal ultrasound)

2. A **lower risk of scar defect formation**

These assessments will be made at **6–8 weeks** and **6–7 months** after your cesarean section.

SECTION C: WHY YOU ARE BEING INVITED

You are being invited to participate because:

- This will be your **first cesarean section** (no prior uterine surgery)
- You are carrying **a single baby**
- You are at least **37 weeks pregnant**
- You meet all the medical requirements to participate safely

We aim to enroll **384 women** in this study at CHU Hédi Chaker, Sfax.

SECTION D: WHAT PARTICIPATION INVOLVES

If you agree to participate, here is what will happen:

Step 1: Randomization

You will be **randomly assigned** to receive either the single-layer or the double-layer uterine closure technique. This assignment is made by a computer program — **neither you nor your surgeon can choose** which technique you receive. This is done to ensure that the comparison between the two groups is fair and unbiased.

You will not be told which technique was used for you during the study. This is to ensure that the doctors performing your ultrasound assessments do not know which group you are in, which guarantees unbiased measurement of results.

Step 2: Your Cesarean Section

Your cesarean section will proceed **exactly as planned**. The only modification is in how the uterus is stitched closed — following the randomly assigned technique. All other steps of your surgery remain entirely standard and unchanged.

The assignment of your technique will be made **only after your baby and placenta have been delivered**, immediately before the surgeon closes your uterus.

Step 3: Postoperative Hospital Care

You will receive standard postoperative care as per the hospital's protocol, including blood tests on the first day after surgery to monitor your hemoglobin level, wound monitoring, and standard discharge criteria.

Step 4: Follow-Up Consultations

You will be asked to return for **two follow-up visits**:

Visit	Timing	Content
Visit 1	6–8 weeks after surgery	Transvaginal ultrasound + clinical examination + symptom questionnaire
Visit 2	6–7 months after surgery	Transvaginal ultrasound + symptom questionnaire (**main study assessment**)

What is a Transvaginal Ultrasound (TVUS)?

A transvaginal ultrasound is a standard gynecological examination in which a small, smooth probe — approximately the width of a finger — is gently inserted into the vagina. This probe uses **sound waves (not radiation)** to produce detailed images of the uterus and uterine scar.

This is a **safe, routine, and commonly performed** gynecological examination. Most women experience only **mild pressure or discomfort** during the procedure, which lasts approximately 10–15 minutes. The examination is ideally performed **around Day 7–14 of your menstrual cycle** for the best visualization of the scar.

Step 5: Standardized Symptom Questionnaire

At each follow-up visit, a structured questionnaire will be completed to assess any symptoms you may be experiencing, including unusual bleeding, spotting between periods, pelvic pain, painful periods, or discomfort during intercourse.

SECTION E: RISKS AND DISCOMFORTS

Risks Related to Your Cesarean Section

Both closure techniques are **well-established and considered equally safe**. Participating in this study does not expose you to any additional surgical risk beyond that of a standard cesarean section.

Standard cesarean section risks (present regardless of study participation) include:

- Bleeding, occasionally requiring a blood transfusion
- Wound or uterine infection
- Injury to adjacent organs (bladder, bowel) — rare
- Blood clots in the legs or lungs — rare
- Anesthesia-related risks

Risks Related to the Transvaginal Ultrasound

- **Mild, brief discomfort** or pressure during probe insertion
- **Very rarely**, light vaginal spotting immediately afterward (resolves spontaneously)
- **No radiation exposure**

There are no known additional risks specific to your participation in this research study beyond those described above.

SECTION F: POTENTIAL BENEFITS

Benefits to You Personally

- You will receive **specialized monitoring of your uterine scar** over 6–7 months — this type of detailed scar assessment is not routinely offered in standard postpartum care
- If a scar defect or thinning is detected, you will be informed promptly and appropriately referred for follow-up or management

Benefits to Society and Future Patients

- Your participation will contribute to generating **high-quality scientific evidence** that will guide surgical decision-making for thousands of women undergoing cesarean sections, potentially improving long-term outcomes for future patients

SECTION G: ALTERNATIVES TO PARTICIPATION

Your sole alternative is to **decline participation**. In that case, your cesarean section will be performed using your surgeon's standard preferred technique. You may freely ask your surgeon which technique they routinely use. You will still receive full standard postoperative care.

SECTION H: CONFIDENTIALITY AND DATA PRIVACY

All personal and medical information collected in the context of this study is treated with the **strictest confidentiality**:

- You will be assigned a **unique anonymous identification number** — your name will never appear in research records or databases
- Your data will be stored in a **secure, password-protected system** accessible only to authorized study personnel
- Published research results will **never identify you personally**
Your information will **not be shared** with insurance companies, employers, or any other third parties
- Your data will be **retained for 15 years** following study completion, as required by research regulations, after which it will be securely destroyed

Your anonymized data may be reviewed by:

- The **Institutional Ethics Committee** (for audit or oversight purposes)
- **Regulatory health authorities** (if legally required)

SECTION I: VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

Your participation is **completely voluntary** at all times. You have the right to:

- **Refuse to participate** at any time, without giving any reason, and without any negative consequence for your medical care
- **Withdraw from the study** at any time after enrollment, without penalty and without affecting the quality of care you receive
- **Request deletion of your data** from the study database at any time prior to final data analysis

If you withdraw, data collected up to that point may be retained for analysis if you provide explicit consent for this; otherwise, your data will be removed.

SECTION J: COMPENSATION AND COSTS

There is **no financial payment** for participation in this study. All study-related examinations — including the transvaginal ultrasound assessments at follow-up visits — are provided **at no cost to you**. Transportation expenses and other personal incidental costs are **not reimbursed** unless specifically agreed upon in writing.

SECTION K: CONTACT INFORMATION

If you have any questions, concerns, or complaints about this study at any time, please contact:

Principal Investigator:

- Dr. [Larbi Nizar], MD
- Department of Obstetrics and Gynecology, CHU Hédi Chaker, Sfax, Tunisia
- Tel: [+21693726918]
- Email: [dr.larbinizar.obgyn@gmail.com]
- Available: Monday–Friday, 08:00–16:00

SECTION L: DECLARATION OF INFORMED CONSENT

By signing below, I confirm that:

- I have read and understood all sections of this Informed Consent Form (Version 2.0, January 2025)
- I have had sufficient time to reflect on my participation and have had all my questions answered satisfactorily
- I understand that my participation is **entirely voluntary** and that I may withdraw at any time without consequence
- I understand that I will **not be told which surgical technique** was used for me during the study period
- I agree to attend the follow-up consultations at **6–8 weeks** and **6–7 months** postpartum
- I agree to undergo **transvaginal ultrasound examinations** at both follow-up visits
- I understand how my personal data will be **used, stored, and protected**

- **I freely, voluntarily, and fully consent to participate in this research study**

PARTICIPANT

FULL NAME (PRINT CLEARLY):	_____
SIGNATURE:	_____
DATE:	_____
CONTACT TELEPHONE:	_____

WITNESS

(Required if participant is unable to read or write)

Full Name (Print clearly):	_____
Relationship to participant:	_____
Signature:	_____
Date:	_____

INVESTIGATOR / PERSON OBTAINING CONSENT

I confirm that I have clearly explained the nature, purpose, duration, procedures, risks, and benefits of this study to the participant in language she could understand. The participant has had the opportunity to ask questions and has been given sufficient time to make a voluntary and informed decision.

FULL NAME (PRINT CLEARLY):	_____
TITLE / ROLE:	_____
SIGNATURE:	_____

DATE:	_____

📋 A signed copy of this Informed Consent Form will be provided to the participant for her personal records. The original signed copy will be retained in the study file.

January 2025 | CHU Hédi Chaker, Sfax, Tunisia