São Paulo State University (UNESP) – "Júlio de Mesquita Filho"

Botucatu Medical School – Department of Pathology

Laboratory of Immunopathology of the Maternal-Fetal Relationship

Research Project

Systematic Screening of Lower Genital Tract Infections in Pregnant Women for Gestational and Neonatal Outcomes: a Randomized Controlled Trial

NCT Number:NCT07592286

March 16th 2026

TALE — Minor Participant

Project Title: Systematic Screening for Lower Genital Tract Infections in Pregnant Women for Gestational and Neonatal Outcomes: a randomized controlled trial

Principal Investigator: Rita de Cássia Fossati Silveira Evaldt
Institution: Federal University of Pampa – UNIPAMPA – Uruguaiana Campus / UNESP
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You are being invited to take part in a health research study being conducted by the Federal University of Pampa. This research aims to better understand whether some tests performed during prenatal care can help prevent problems during pregnancy and after the baby is born. The objective of the study is to evaluate whether screening for genital infections, even when they do not cause symptoms, can help reduce pregnancy complications and improve the health of the mother and the newborn.

If you agree to participate, the following will occur:

- you will answer some simple questions about your health and your pregnancy;
- during the medical appointment, gynecological examinations similar to those performed during prenatal care may be carried out;
- samples of vaginal content may be collected during follow-up appointments;
- once in each trimester of pregnancy, material may be collected from the cervix;
- after delivery, information about you and your baby may be obtained from the hospital medical records.

These procedures are part of health care and do not involve tests different from those already performed during prenatal care. Each appointment will last approximately 20 minutes. The possible discomforts of the research include mild discomfort during the gynecological examination or embarrassment when answering some questions. If this happens, you may ask to interrupt the examination or choose not to answer any question. There will be no punishment or harm to your health care. The expected benefits include the possibility of early identification and treatment of infections that often have no symptoms, contributing to a safer pregnancy.

Considering that this research involves different stages of data collection, I declare that I am aware of and authorize my participation in the following activities:

( ) Clinical interview with collection of sociodemographic, obstetric, and clinical information
( ) Collection of vaginal material at all prenatal appointments
( ) Collection of endocervical material once in each gestational trimester
( ) Use of results from routine prenatal laboratory tests
( ) Collection of information about the pregnant woman and the newborn from hospital medical records after delivery

Your participation is voluntary. Even if your parents or legal guardians authorize it, you may decide not to participate or may withdraw at any time.

Your name will not be disclosed. All information collected will be kept confidential and used only for research purposes.

If you have any questions, you may talk to the principal investigator, your family, or the health professionals before making your decision.

If you agree to participate, please sign below:

Participant's name: _____
Participant's signature: _____

Name of the principal investigator: Rita de Cássia Fossati Silveira Evaldt
Signature of the principal investigator: _____

Uruguaiana, ____ day of _____, 2026

In case of questions about research ethics, please contact:

Research Ethics Committee – CEP/UNIPAMPA
Phone: +55 55 3911-0202 – Extension 8025
E-mail: cep@unipampa.edu.br