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Preparatory study on interest of vaginal probiotics on mother's health issues after breaking waters in mid-term pregnancy

Submission date
29/10/2025

Recruitment status
Recruiting

Registration date
16/03/2026

Overall study status
Ongoing

Last Edited
08/04/2026

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Premature rupture of fetal membranes before labor (PPROM) accounts for 30% of premature births. As PPROM is strongly associated with vaginal infection, antibiotics are recommended between rupture and birth. The addition of vaginal probiotics (VP) may stabilize the vaginal microbiota. This study aims to find out whether a larger study evaluating the impact of VP on newborn outcomes (death and illness rates) is feasible.

Who can participate?
Women aged 18 years and over, hospitalized for PPROM (24-32 weeks of gestation), single pregnancy and expectant management

What does the study involve?
Participants are randomly allocated to placebo or vaginal probiotics. The participant takes one intravaginal capsule once a day at bedtime between inclusion in the study until delivery. Vaginal discharge samples are taken once a week and two infant stool samples will be collected. Questionnaires are completed at inclusion and at the end of the study.

What are the possible benefits and risks of participating?
Certain benefits may derived from participating in the study, but there is no guarantee. Known side effects include increased vaginal discharge (rare, minor severity) and external genital irritation (rare, minor severity) and a possible internal irritation (rare, minor severity). Unknown risks may occur. An infection may also occur, but this undesirable effect is very rare (serious severity) and known cases have occurred in people who took probiotics orally and had a weakened immune system.

Where is the study run from?
Centre Hospitalier de l'Université de Montréal (CHUM) (Canada)

When is the study starting and how long is it expected to run for?
December 2025 to September 2027

Who is funding the study?
Canadian Institutes of Health Research (CIHR) (UK)

Who is the main contact?
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Contact information

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT06965049

Protocol serial number
MP-02-2025-12298

Study information

Scientific Title
Multicentric randomized controlled trial of feasibility testing the association between antibiotics and vaginal probiotics for patients with premature and preterm rupture of membranes between 24 and 32 weeks of amenorrhea

Acronym
PROB-PROM

Study objectives
In order to prepare a largest multicenter randomized controlled trial (RCT), we aim to evaluate if this study is feasible (recruitment rate, adherence to treatment, attrition). As a fundamental approach, the study aim to compare the presence of probiotics in vaginal microbiota and neonatal samples between groups. Also, the study wants to measure the impact of vaginal probiotics (VP) on the vaginal microbiota and the neonatal intestinal microbiota.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/10/2025, Research Ethics Board of the Centre de recherche du Centre hospitalier de l'Université de Montréal (850 rue St Denis, Montréal, H2X 0A9, Canada; +1 (0)514 890 8000 14485; ethique.recherche.chum@ssss.gouv.qc.ca), ref: 2025-12298

Primary study design
Interventional

Study design
Multicenter interventional randomised controled trial of feasibility in intention to treat double-blinded with two parallel arms

Study type(s)
Treatment, Other

Health condition(s) or problem(s) studied
Premature and preterm rupture of membranes for pregnancy of 24-32 weeks of amennorhea

Interventions
Randomization will be programmed in SAS by a statistician and performed online using the REDCap software system. Participants are assigned 1:1 to placebo or vaginal probiotics as a mix of probiotics strain. The participant takes one intravaginal capsule once a day at bedtime between inclusion in the study until delivery.

Intervention Type
Other

Primary outcome(s)
The validity of the essay measuring the recruitment rate, adherence to treatment and attrition rate at inclusion and throughout the study

Key secondary outcome(s)

A metagenomic analysis will enable the study of microbiota (shotgun sequencing) using the samples throughout the study. The use of single nucleotide variants will study the presence of VP during the intervention period (study product intake period).

Completion date
15/09/2027

Eligibility

Key inclusion criteria
1. Person of female sex
2. ≥18 years of age
3. Mono-fetal pregnancy
4. Treated for PPROM between 24 and 32 weeks of gestation with expectant management in one of the study centers
5. With latency period between 12 hours and <7 days
6. Speaking and able to read French or English

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Presence of active labor
2. Situation contraindicating expectant management (e.g., infection)
3. Significant malformation, chromosomal anomaly, or fetal death
4. Signs of fetal distress
5. Allergy or intolerance to any of the following substances: vitamin C (ascorbic acid), magnesium stearate, maltodextrin, gelatin, yeast, sucrose, trehalose
6. Allergy to soy or lactose
7. Weakened immune system (e.g., AIDS, prolonged corticosteroid treatment, etc)
8. Vaginal probiotics intake 15 days before study inclusion
9. Oral probiotic intake 30 days before study inclusion

Date of first enrolment
15/03/2026

Date of final enrolment
15/09/2026

Locations

Countries of recruitment
Canada

Study participating centre
Centre hospitalier de l'Université de Montréal (CHUM)
850 St-Denis Street
Montreal
Canada
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Sponsor information

Organisation
Centre hospitalier universitaire de Montréal (CHUM)

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (Centre hospitalier de l'Université de Montréal repository). The datasets generated during and/or analysed during the current study will be available upon request from Dr Jean-Charles Pasquier (jean-charles.pasquier@umontreal.ca).

IPD sharing plan summary
Available on request, Stored in non-publicly available repository