

Can a probiotic taken by mouth reduce group B streptococcus in the vagina during pregnancy?

Submission date 10/08/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/08/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 10/08/2026	Condition category Infections and Infestations	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

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Principal investigator, Scientific, Public

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Additional identifiers

Study information

Scientific Title

Targeting vaginal microbiota during pregnancy: oral *Lactobacillus crispatus* M247 and vaginal Group B streptococcus colonization

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 21/03/2025, Ethics Committee of Elias University Emergency Hospital (17 Mărăști Blvd, Bucharest, 011461, Romania; +40213161600; contact@spitalul-elias.ro), ref: 1835

Primary study design

Interventional

Allocation

Non-randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Prevention

Study type(s)

Health condition(s) or problem(s) studied

Prevention of Group B Streptococcus colonization in pregnancy

Interventions

Participant with a positive vaginal GBS culture at 24-26 weeks of gestation were allocated to one of two parallel groups according to participant preference following standardised counselling; no randomisation and no placebo were used.

Intervention group: oral *Lactobacillus crispatus* M247, 20 billion CFU once daily, for eight weeks, self-administered at home, started after confirmation of vaginal GBS colonisation at 24-26 weeks of gestation. Participant obtained the commercially available product independently from community pharmacies.

Control group: standard antenatal care without probiotic supplementation.
Both groups followed the same study schedule, with a repeat vaginal GBS culture at 34-36 weeks of gestation. Adherence was assessed by self-report at routine antenatal visits. Laboratory personnel processing the cultures were unaware of group allocation; participants and clinical investigators were not blinded.

Intervention Type

Supplement

Primary outcome(s)

1. Persistent vaginal Group B Streptococcus colonisation measured using vaginal culture for Streptococcus agalactiae, collected from the lower third of the vagina, processed by selective enrichment broth followed by subculture on blood and chromogenic agar, with species confirmation by MALDI-TOF mass spectrometry; reported qualitatively as present or absent, at 34-36 weeks of gestation

Key secondary outcome(s)

1. Adherence to oral probiotic supplementation measured using participant self-report of daily probiotic intake, recorded at routine antenatal visits, at 34-36 weeks of gestation
2. Adverse events associated with oral probiotic supplementation measured using participant-reported adverse events recorded at routine antenatal visits, at 34-36 weeks of gestation

Completion date

10/12/2025

Eligibility

Key inclusion criteria

1. Pregnant women aged 18 years or older
2. Confirmed viable pregnancy
3. Positive vaginal culture for Group B Streptococcus at 24-26 weeks of gestation
4. Written informed consent

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Upper age limit

39 Years

Sex

Female

Total final enrolment

Key exclusion criteria

1. Use of systemic antibiotics
2. Concomitant probiotic use
3. Use of intravaginal antimicrobials
4. Major immunosuppression

Date of first enrolment

24/03/2025

Date of final enrolment

30/09/2025

Locations**Countries of recruitment**

Romania

Sponsor information**Organisation**

Elias University Emergency Hospital, Bucharest, Romania

Funder(s)**Funder type****Funder Name**

Investigator initiated and funded

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not expected to be made available