# Study to assess the preventive effect of new probiotic strain on lactational mastitis.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25986

**Source**
Nationaal Trial Register

**Brief title**
PREMIUM

**Health condition**

Healthy breastfeeding women.

### Sponsors and support

**Primary sponsor:** Nutricia Research BV
Uppsalalaan 12
3508 TC Utrecht
Nederland
tel + 31 30 2095000
**Source(s) of monetary or material Support:** Nutricia Research BV
Uppsalalaan 12
3508 TC Utrecht
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## Intervention

## Outcome measures

### Primary outcome

Incidence (hazard) rate of mastitis.

### Secondary outcome

- Count of recurrent episodes of mastitis;
- Incidence (hazard) rate of breastfeeding withdrawal (complete/partial discontinuation).

# Study description

### Background summary

In this study the preventive effect of a new probiotic strain on mastitis in healthy breastfeeding women will be investigated. After screening subjects will receive either the probiotic supplement or the placebo supplement, which they need to take until 12 weeks after delivery. In case no mastitis occurs relevant study information will be collected at several pre-defined time points during the study. In case of a (suspected) mastitis, additional contact moments will be scheduled. During the course of the study at several time points faecal and breast milk samples need to be collected for laboratory analysis.

### Study objective

Study will demonstrate the preventive effect of a new probiotic strain on mastitis in healthy breastfeeding women.

### Study design

Visit 1 screening & baseline; Visit 2 (V2) between week 2 and week 7; Call 1 V2 + 6 weeks; Visit 3 V2+ 12 weeks. In case of (suspected) mastitis additional visits and a call are scheduled.

### Intervention

Intervention group: probiotic supplement; control group: placebo supplement.
Duration of intervention: varies per subject from 16 to 21 weeks.

# Contacts

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# Eligibility criteria

## Inclusion criteria

- Healthy pregnant, adults (> 18 years of age);
- Before/during the 35th week of pregnancy;
- Intending to breastfeed her infant;
- Written informed consent.

## Exclusion criteria

- Pre-gravid body mass index (BMI)<18 or >30;
- Use of probiotic supplements during the third trimester of current pregnancy;
- Enhanced chance of premature delivery (before 37 weeks of gestation);
- Current or previous illnesses which could interfere with the study, like other mammary pathologies (e.g. abscesses, Raynaud¡¯s syndrome, breast cancer);
- Short bowel syndrome;
- Impaired intestinal epithelial barrier (e.g. diarrheal illness, intestinal inflammation);
- Serious underlying disease predisposing to infection (e.g. HIV, auto-immune diabetes, multiple organ failure, malignancy, severe burns, severe acute pancreatitis);

- Heart failure and cardiac medical history (e.g artificial heart valve, medical history of infectious endocarditis, rheumatic fever and cardiac malformation);
- History of aggressive immunosuppressive therapy (e.g. radiotherapy, cancer chemotherapy);
- Traumatic injury of the gastro-intestinal tract;
- Surgery, including dental surgery, within one month prior to inclusion (V1) ;
- Investigator's uncertainty about the willingness/ability of the subject to comply with protocol requirements;
- Participation in any other clinical trial within two weeks prior to entry into the study.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Double blinded (masking used) |
| Control: | Placebo |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-04-2014 |
| Enrollment: | 300 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 07-01-2014 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL4243 |
| NTR-old | NTR4388 |
| Other | Nutricia Research : PLB.1.C/B |

# Study results

**Summary results**
Not applicable