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

Gepubliceerd: 07-01-2014 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25986

Bron
Nationaal Trial Register

Verkorte titel
PREMIUM

Aandoening

Healthy breastfeeding women.

Ondersteuning

Primaire sponsor: Nutricia Research BV
Uppsalalaan 12
3508 TC Utrecht
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Overige ondersteuning: Nutricia Research BV
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Incidence (hazard) rate of mastitis.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
Not applicable