Effect of a new synbiotic mixture of short chain galacto-oligosaccharides, long chain fructo-oligosaccharides and Bifidobacterium strain on the gut microbiota of caesarean delivered infants.

Gepubliceerd: 15-12-2009 Laatst bijgewerkt: 18-08-2022

The study will investigate the effect of a synbiotic test product compared to a control product on the composition and metabolic activity of the gut microbiota of C-section delivered infants.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25311

Bron
Nationaal Trial Register

Verkorte titel
Julius

Aandoening

Healthy term born neonates born to healthy pregnant mothers either by caesarean section or vaginally

Ondersteuning

Primaire sponsor: Danone Research – Centre for Specialised Nutrition
Overige ondersteuning: Danone Research – Centre for Specialised Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Exploratory Parameters:
1. Composition and metabolic activity of the gut microbiota, assessed by Fluorescent in situ hybridization (FISH) and real time PCR (RT-PCR);
2. Gastrointestinal tolerance;
3. (Serious) adverse events;
4. Anthropometry: anthropometric data will be measured/recorded according to the visits.

Toelichting onderzoek

Achtergrond van het onderzoek

To investigate the effect of the test product compared to the control product on the development of the gut microbiota, caesarean delivered infants will be randomly allocated to either the intervention group receiving the test product or to the control group receiving a placebo product. The reference group will be represented by vaginal delivered, breastfed infants. The in- and exclusion criteria are chosen in a way that only healthy mothers and healthy term born neonates are included in the study. All children will be followed up for 4 weeks after end of intervention. Stool samples will be analysed and safety parameters will be assessed via diary and at the hospital visits.

Doel van het onderzoek

The study will investigate the effect of a synbiotic test product compared to a control product on the composition and metabolic activity of the gut microbiota of C-section delivered infants.

Onderzoeksopzet

1. 8 personal visits troughout the study duration;

2. 9 stool sample collections throughout the study duration.

Onderzoeksproduct en/of interventie

Duration of intervention: 16 weeks

1. Intervention group:

The participants will receive additional to regular feeding a supplement containing Pre- and Probiotics.

2. Control group:

The control products will be comparable to supplement 1 (excluding the active compound).

The children born vaginally give a reference group. They are breastfed.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Healthy term born neonates born to healthy pregnant mothers;

2. Mother is willing and able to comply with the protocol, including refrain from 2 weeks prior to study start (expected date of delivery) and for the duration of the study from the:

A. Use of probiotic supplements and food containing supplemented probiotics;

B. Use of prebiotic or fibre supplements;

C. Participation in any other intervention study.

3. Parents have given written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

For the mothers:

1. Use of antibiotics (except antibiotic treatment related to CS) from 2 weeks prior to delivery for duration of the study;

2. Use of non-steriodal anti-inflammatory drugs (NSAIDs) from 2 weeks prior to delivery for duration of the study;

3. Fever 38.5 degrees or more during the last week before birth;

4. Blood pressure systolic ¡Ý 160 mm Hg and diastolic ¡Ý 100 mm Hg;

5. Occurrence of Eclampsia and Preeclampsia during the pregnancy;

6. Antenatal steroid treatment;

7. Antenatal antibiotics treatment (2 weeks before birth);

8. Diabetes mellitus requiring insulin treatment;

9. Hyperthyroidism during pregnancy;

10. Pathologic birth presentation;

11. Abnormal Cardiotocogram for more than 2 hours at day of delivery;

12. Preterm birth before 37th week of gestation;

13. Probiotic and prebiotic supplementation during the last 2 weeks of gestation;

14. Mothers treated for infertility;

15. Placenta implementation;

16. Any known atopic diseases or food allergies in family history;

17. Investigator¡¯s uncertainty about the willingness or ability of the subject to comply with the protocol requirements.

For the neonates:

1. Any known congenital disease which could interfere with the study conduct and assessments;

2. Any serious disease that could interfere with the study conduct and assessments;

3. Abnormal birth weight (normal ranges: girls 2.7 ¨C 5 kg; boys 2.9 ¨C 5.2 kg);

4. Apgar score < 7 after 10 min;

5. Any medical condition requiring antibiotic therapy after birth.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-12-2009
Aantal proefpersonen:	180
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	15-12-2009
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	NL2026
NTR-old	NTR2143
Ander register	Danone Research B.V. : Cae.1.C/B
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A