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.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25311

Source
Nationaal Trial Register

Brief title
Julius

Health condition

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

Sponsors and support

Primary sponsor: Danone Research – Centre for Specialised Nutrition
Source(s) of monetary or material Support: Danone Research – Centre for Specialised Nutrition

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

1. 8 personal visits troughout the study duration;

2. 9 stool sample collections throughout the study duration.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-12-2009
Enrollment:	180
Type:	Anticipated

Ethics review

Positive opinion

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

Study results

Summary results
N/A