Effect of a new synbiotic infant formula on the gut microbiota of infants delivered by Caesarian Section.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23445

Source
NTR

Brief title
Julius SN

Health condition

Healthy term born infants, born to healthy pregnant women

Sponsors and support

Primary sponsor: Danone Research
Source(s) of monetary or material Support: Danone Research

Intervention

Outcome measures

Primary outcome

The effect of the two test products compared to the effect of the control product in infants delivered by Caesarean section on the total bifidobacteria count of the gut microbiota.

Secondary outcome

The effect of the two test products compared to the effect of the control product in infants delivered by Caesarean section on the bifidobacteria distribution, the composition of other members of the gut microbiota and metabolic activity.

For the reference group bifidobacteria distribution, the composition of other members of the gut microbiota and metabolic activity will be measured in.

Study description

Background summary

Subjects eligible for participation will be identified before birth and informed consent will be obtained. The mothers will be informed about the benefit of breastfeeding. Immediately after birth, the neonates which are born by CS will be randomised to one of the 2 intervention groups or the control group by using sealed envelopes, no matter whether or to what extend the mother will breast- or formula feed. Whenever formula is desired during the study for example when breast feeding is not possible for any reason, when switching from breast milk to formula or mixed feeding, the infant will receive study formula according to randomisation.

The intervention period will last for 16 weeks according to the feeding regimen described above. After 16 weeks the infants will be followed up for 6 weeks without giving the study products.

Neonates, born vaginally whose mothers' intent to breast feed as long as possible will not be randomised and included in the reference group.

If the study results show significant differences regarding the total bifidobacteria (Test product II vs Control product, Per Protocol Set population) a follow up study will be performed until the infants are 7 years including one or both intervention groups (depending on the results), the control group and the reference group.

The composition of the gut microbiota will be assessed by analysing the first meconium, faecal samples at day 3, day 5, day 14, week 4, 8, 12, 16 and at week 22. In addition faecal short chain fatty acids (SCFA), faecal lactate, faecal pH, faecal sIgA and faecal calprotectin will be determined.
Safety parameters will be assessed (gastrointestinal tolerance, fever, medication, (serious) adverse events and microbiological analysis of blood (blood culture) in case of fever ≥ 38.5°C lasting for at least 3 days). For the assessment of anthropometric data (length, weight and head circumference) examinations will be performed starting directly after birth followed by examinations before discharge of hospital (in week 1), week 8, 16, 22 after birth.

Gastrointestinal tolerance, stool characteristics, illnesses, doctors' diagnosis, use of medication/vaccination and feeding regimen will be recorded in a diary filled in by the mother on a daily basis. (Serious) Adverse events will be recorded upon occurrence throughout the entire study period.

Study objective

To investigate the effect of the two test products compared to the effect of the control product in infants delivered by Caesarian Section on the total bifidobacteria count of the gut microbiota.

Study design

Visits:

1. Screening 1 is scheduled any time before planned/expected birth;

2. Visit 1 (screening 2/randomisation) right after birth;

3. Visit 2 before discharge of hospital, approximately day 3 after birth;

4. Visits 3 and 4 (+ blood sample) are scheduled 8 and 16 weeks from birth +/- 4 days;

5. Visit 5 is scheduled in the timeframe of 22 weeks after birth +/- 4 days.

Faecal samples:

1. Meconium before first test product administration, if possible;

2. Faecal sample 1 should be taken anytime on day 3 of age;

3. Faecal sample 2 should be taken anytime on day 5 of age;

4. Faecal sample 3 should be taken at 14 days of age +/- 1 day;

5. Faecal sample 4 should be taken at 4 weeks of age +/- 2 days;

6. Faecal sample 5 should be taken at 8 weeks of age +/- 3 days;

7. Faecal sample 6, should be taken at 12 weeks of age +/- 3 days;

8. Faecal sample 7 should be taken at 16 weeks of age +/- 3 days;

9. Faecal sample 8 should be taken at 22 weeks of age +/- 3 days.

Intervention

Mothers who gave birth by CS will be randomised to one of the three intervention groups:

1. Investigational group I receiving formula with a mixture of prebiotics during the first 16 weeks of life;

2. Investigational group II receiving formula with a mixture of synbiotics during the first 16 weeks of life;

3. Control group receiving comparable infant standard formula with no supplementation of pre- or synbiotics during the first 16 weeks of life.

In parallel, one group of infants who are delivered vaginally and breast fed as long as possible will be studied. These infants will not be randomised.

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Eligibility criteria

Inclusion criteria

1. Healthy term born infants, born to healthy pregnant women;

2. Parents are willing and able to comply with the protocol;

3. Mother is willing to refrain from participation in any other intervention study;

4. Mother is willing to refrain 2 weeks prior to expected date of delivery from use of probiotic supplements or food products with added probiotics and use of dietary supplements containing prebiotics or dietary fiber;

5. Mothers who are breastfeeding are willing to refrain from the above mentioned supplements, antibiotics and non-steroidal anti-inflammatory drugs (NSAIDs) while breastfeeding, if possible;

6. Written informed consent from parents.

Exclusion criteria

For the mothers:

1. Fever ≥ 38.5° during the last week before birth;

2. Preterm birth before 37th week of gestation;

3. Occurrence of Eclampsia and Preeclampsia during the pregnancy;

4. Antenatal steroid treatment, except antenatal steroid treatment to prevent premature delivery;

5. Use of non-steroidal anti-inflammatory drugs (NSAIDs);

6. Antenatal antibiotics treatment (2 weeks before birth, except for prophylactic use during Caesarean delivery);

7. Diabetes mellitus requiring insulin treatment during pregnancy;

8. Uncontrollable Hyperthyroidism during pregnancy;

9. Severe abnormal Cardiotocogram for more than 2 hours at day of delivery leading to emergency CS;

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

11. Mothers treated for subfertility/infertility using assisted reproductive technologies;

12. 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: 2.25 – 4 kg);

4. Apgar score <7 after 5 min.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2011
Enrollment:	168
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-04-2011
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	NL2701
NTR-old	NTR2838
Other	Danone Research : Cae.1.C/C
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A