Toddlers receiving synbiotics after antibiotics

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20358

Source
Nationaal Trial Register

Brief title
TOBBI

Health condition

Received amoxicilline treatment for treatment of bacterial infection

Sponsors and support

Primary sponsor: Wageningen University
Source(s) of monetary or material Support: TKI & Danone-Nutricia

Intervention

Outcome measures

Primary outcome

- Proportion of all species belonging to the genus Bifidobacterium out of total species, at t=0, t=21, t=42 and t=84 days, based on qPCR, ITS and 16s rDNA sequencing data.
- Composition of all species belonging to the genus Bifidobacterium at t=0, t=21, t=42 and t=84 days, based on qPCR, ITS and 16s rDNA sequencing data.

Secondary outcome

1a. Proportion of bifidobacteria by qPCR at t=0, t=7, t= 14, t=28, t=35, t=49, t=56, t=63, t=70, t=77 and t=84 days;.
b. Total microbiota composition by 16s rDNA sequencing at t=0,t=21, t=42 and t=84 days;
c. Faecal pH and short-chain fatty acid (SCFA) levels of faecal samples at t=0 to t=21, t=42 and t=84 days;
d. Stool characteristics: consistency and frequency as reported in a weekly diary using modified Bristol Stool Form Scale;
e. Gastrointestinal symptoms, deviating from normal, as documented in a weekly diary.
2. The proportion and composition of bifidobacteria and total microbiota composition in the intervention- and control group compared to the age matched group.

Other endpoints
1. The amount of study product and cow's milk consumed for compliance, as reported in the diary;
2. Habitual dietary intake assessed with an FFQ of participants and its association with proportion bifidobacteria at 42 and 84 days;
3. Habitual dietary intake assessed with an FFQ of the participants and its association with microbiota composition at 42 and 84 days;
4. Habitual dietary intake assessed with an FFQ of the participants and its association with stool characteristics at 42 and 84 days;

Explorative study endpoints
• Total microbiota composition, bifidobacteria specific ITS sequence, faecal pH and SCFA composition, at all timepoints;
• Total microbiota composition and bifidobacteria specific ITS sequence at t=0 to t=21, t=42 and t=84 days assessed per breastfeeding duration group (e.g. no breastfeeding, breastfeeding up to 3, 6, 9 or 12 months after birth).

Study description

Background summary

Antibiotics are prescribed for bacterial infections. Although they help to fight the pathogenic bacteria, antibiotics are also known to disrupt the gut microbiota: the trillions of bacteria and other microorganisms that live in the gut. These bacteria are very important as they help digest our food: they can convert undigested food into energy and other useful substances such as vitamins. They also strengthen our immune system.
The stability and composition of the gut microbiota is vital for health and wellbeing throughout life. Of special importance is the timeframe from age 0-3 years, as the microbiota composition develops and matures in babies and toddlers until it resembles that of the adult composition around the age of 2 to 3 years. Typical factors that can hamper the process of microbiota maturation are premature birth as well as formula feeding, undernutrition and

antibiotic use.
There are several ways to restore the gut microbiota after a disruption as caused by antibiotics. An example is using a food supplement that contains probiotics: large amounts of beneficial bacteria. It is also possible to help restore the gut microbiota with prebiotics; fibers that stimulate the good bacteria in the gut to grow. A mix of probiotics and prebiotics is also possible, we call this a synbiotic.
In the TOBBI study we will assess the disruptive effect of antibiotics on the bacteria that live in the gut of toddlers. We will also assess whether this effect is less when a synbiotic is used after the antibiotics. In this study, 63 toddlers aged 1-2 year old will consume a young child formula that is supplemented with synbiotics, after a course of the antibiotic amoxicillin. The effect of the synbiotic will be compared to a control group of 63 toddlers who will consume regular cow's milk after a course of amoxicillin. We will assess among others the microbiota composition in stool samples, evaluate gastro-intestinal symptoms and the effect of habitual dietary intake on the microbiota composition.
To study the composition of the microbiota in healthy toddlers before antibiotic treatment, a healthy age-matched control group of 30 toddlers will be included to provide one stool sample. These samples will provide information about the gut microbiota composition of healthy toddlers and will be used as an indication for the composition of the study participants before taking the antibiotics.

We expect that the bacterial composition in the gut may recover faster when the young child formula supplemented with synbiotics is consumed by the children.

A sub-study will be conducted to explore cross-sectional associations between the diet of the parents / caretakers and that of the child.

Study objective

If a young child formula supplemented with synbiotics is consumed after a course of amoxicillin by toddlers, a more rapid return to normal occurs.

Study design

Home visits at start and end of study;
Study duration for 1 participant = 12 weeks;
The intervention period is 6 weeks, followed by 6 weeks run-out.

Other timepoints:
- Daily reporting of consumed amount of study-and control product during the first 6 weeks.
- Weekly stool sampling, reporting of gastro-intestinal symptoms & adverse events
- Phone calls at week 1, 6 and 9
- Reporting the consumption of food and drinks by the participant in a food diary for 3 days in week 7 and 8
- Completion a Food Frequency Questionnaire about both parents / caregivers and the study participant, around week 9

Intervention

Young child formula supplemented with synbiotics vs regular cow's milk

Contacts

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Eligibility criteria

Inclusion criteria

Study participants (n=126):
1. Written informed consent obtained from both caregivers;
2. Caregivers are willing to comply with the requirements of the study;
3. Age 1-2 year old at the time of enrollment;
4. Drinks cow’s milk (non-fat, semi-skimmed or full fat) on a daily basis;
5. Received a prescription for amoxicillin.

Age-matched control group (n=30):
1. Written informed consent obtained from both caregivers;
2. Caregivers are willing to comply with the requirements of the study;
3. Age 1 year old;

Exclusion criteria

Study participants (n=126):
1. Any GI complaints, known structural GI abnormalities, or previous GI surgery;
2. Clinically significant cardiac, vascular, liver, pulmonary, psychiatric disorders, severe renal insufficiency, human immunodeficiency virus infection, acquired immunodeficiency syndrome, hepatitis B or C or abnormalities of haematology, urinalysis, or blood biochemistry;
3. Known to have an allergy or intolerance to any of the ingredients in the study- or control

product, including lactose and cow’s milk protein;
4. Used pre-or probiotic supplements or food products with added pre- or probiotics (e.g. formula containing GOS or FOS, Activia, Actimel, Yakult, etc.) in the last 7 days before start of the antibiotic treatment;
5. Is receiving breastmilk, or has received breastmilk in the last 7 days before start of antibiotic treatment.

Age-matched control group (n=30):
1. Any GI complaints, known structural GI abnormalities, or previous GI surgery;
2. Clinically significant cardiac, vascular, liver, pulmonary, psychiatric disorders, severe renal insufficiency, human immunodeficiency virus infection, acquired immunodeficiency syndrome, hepatitis B or C or abnormalities of haematology, urinalysis, or blood biochemistry;
3. Known to have an allergy or intolerance to any of the ingredients in the study- or control product, including lactose and cow’s milk protein;
4. Used pre-or probiotic supplements or food products with added pre- or probiotics (e.g. formula containing GOS or FOS, Activia, Actimel, Yakult, etc.) in the last 7 days before start of the antibiotic treatment;
5. Has received any broad-spectrum antibiotic treatment at any time in his/her life.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2021
Enrollment:	156
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 52353
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8996
CCMO	NL75975.081.20
OMON	NL-OMON52353

Study results