

The influence of Maternal Antibiotic use on Microbial colonisation in Infants

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Timing of antibiotic administration during a cesarean section (prior to the cesarean section versus after clamping the cord) has a significant influence on the diversity of the developing neonatal intestinal microbiota and presence of specific...

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

Samenvatting

ID

NL-OMON26831

Bron

Nationaal Trial Register

Verkorte titel

MAMI study

Aandoening

Cesarean section, keizersnede
Vaginal delivery, vaginale partus
Intestinal colonization, intestinale kolonisatie
Microbiota, microbiom
Antibiotics, antibiotica

Ondersteuning

Primaire sponsor: VU medical center

Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. To describe and compare intestinal microbiome colonisation (by means of IS-pro) of neonates born by cesarean section, in terms of timing of antibiotics treatment: prior to caesarean section (NVOG protocol) or after clamping of the umbilical cord (currently used protocol).

Toelichting onderzoek

Doel van het onderzoek

Timing of antibiotic administration during a cesarean section (prior to the cesarean section versus after clamping the cord) has a significant influence on the diversity of the developing neonatal intestinal microbiota and presence of specific bacterial species.

Onderzoeksopzet

- Postnatal age 0 (day of birth)
- Postnatal age 7 days
- Postnatal age 28 days

Onderzoeksproduct en/of interventie

- 20 women will be treated according the current protocol on antibiotic administration (antibiotic administration after clamping of the umbilical cord);
- 20 women will be treated according to the NVOG protocol (administration of antibiotics just prior to skin incision)
- 20 women admitted for outpatient vaginal delivery will be asked to participate in this study (providing baseline characteristics)

From each participating woman, one rectal swab and one vaginal swab will be collected closely prior to delivery.

Directly after delivery, one oral swab will be collected from the neonate. In addition, neonatal fecal samples will be collected on the 1st, 7th and 28th day after birth. Antibiotic levels will

be determined from the umbilical cord blood from women assigned to the antibiotic administration prior to skin incision

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Mother:

- Delivery at a gestational age > 36+6 weeks
- Vaginal or primary cesarean delivery
- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Mother:

- Age < 18 years
- Antibiotic use during pregnancy
- Usage of immunosuppressive drugs up to 3 months prior to delivery
- BMI > 30
- Inflammatory bowel diseases, celiac disease
- Major gastro-intestinal operation in the past (e.g. bowel resection, gastric bypass)
- Diabetes mellitus type1 and 2, and gestational diabetes mellitus insuline dependent)
- intoxications (smoking, alcohol or drugs)

Exclusion after delivery

Mother

- Antibiotic use during first month

Neonate

- Antibiotic use during first month
- Usage of immunosuppressive drugs during first month
- Congenital gastro-intestinal disease
- Gastro-intestinal operation during first month

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind

Controle: Actieve controle groep

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-02-2015
Aantal proefpersonen: 60
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 25-07-2016
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	NL5845
NTR-old	NTR6000
Ander register	: 2014.468

Resultaten