The influence of Maternal Antibiotic use on Microbial colonisation in Infants

No registrations found.

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

Summary

ID

NL-OMON26831

Source
Nationaal Trial Register

Brief title
MAMI study

Health condition

Cesarean section, keizersnede
Vaginal delivery, vaginale partus
Intestinal colonization, intestinal kolonisatie
Microbiota, microbioom
Antibiotics, antibiotica

Sponsors and support

Primary sponsor: VU medical center
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

ƒ{1. To describe and compare intestinal microbiome colonisation (by means of IS-pro) of

neonates born by cesarean section, in terms of timimng of antibiotics treatment: prior to caesarean section (NVOG protocol) or after clamping of the umbilical cord (currently used protocol).

Secondary outcome

ƒ{-To describe and compare intestinal microbiome colonisation of vaginally delivered neonates with those born by caesarean section by means of IS-pro analysis.

- To evaluate effects of maternal vaginal and rectal microbiota composition on neonatal gut microbiota colonisation.

Study description

Study objective

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.

Study design

- Postnatal age 0 (day of birth)

- Postnatal age 7 days

- Postnatal age 28 days

Intervention

- 20 women will be treated according the current protocol on antibiotic administration (antibiotic administration after clampsing 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, oneoral 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

Contacts

Public
VU Medical Center, Department of Obstetrics and Gynaecology,
P.O. Box 7057
J.I.P. Vries, de
Amsterdam 1007 MB
The Netherlands
Scientific
VU Medical Center, Department of Obstetrics and Gynaecology,
P.O. Box 7057
J.I.P. Vries, de
Amsterdam 1007 MB
The Netherlands

Eligibility criteria

Inclusion criteria

Mother:

- Delivery at a gestational age > 36+6 weeks

- Vaginal or primary cesarean delivery

- Written informed consent

Exclusion criteria

Mother:

- Age < 18 years

- Antibiotic use during pregnancy

- Usage of immunosuppresive 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 immunosuppresive drugs during first month

- Congenital gastro-intestinal disease

- Gastro-intestinal operation during first month

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2015
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-07-2016
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	NL5845
NTR-old	NTR6000
Other	: 2014.468

Study results