ZEBRA study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21464

Source
NTR

Brief title
ZEBRA

Health condition

Neonates suspected of infection, microbiome, antibiotic resistance

Sponsors and support

Primary sponsor: Linnaeus Institute
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

1. To assess the short- and long-term prevalence of AMR genes in the microbiome of the gut in infants exposed to broad-spectrum antibiotics in the first week of life compared to controls.

2. To investigate the short- and long-term effects of broad-spectrum antibiotics administered in the first week of life on the composition of the microbiome of the gut in the first 5 years of life compared to controls.

Secondary outcome

To identify which of the recommended and generally used broad-spectrum antibiotic regimens for treating neonatal infections induces least AMR gene selection and disturbance of the microbial composition as compared to non-treated control neonates.

Study description

Background summary

-

Study objective

-

Study design

Samples will be collected 5 times during the first year of life from each participant, either in the clinic or at home.

Intervention

The three most common antibiotic strategies used in the Netherlands will be tested for side-effects on the microbial flora. A control Group will be composed of 44 vaginally born infants or infants born by emergency caesarean section who will be recruited prenatally and followed in parallel through home-visits, receiving no antibiotics in the first week of life (MUIS study, M012-015, NTR3986).

Contacts

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Eligibility criteria

Inclusion criteria

1. Need for empirical antibiotic treatment within the first week of life;

2. Vaginal birth or birth by emergency caesarean section;

3. Term delivery (defined as born after 36 weeks of gestational age).

Exclusion criteria

Major known underlying disease

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-11-2014
Enrollment:	132
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	26-03-2015
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	NL4882
NTR-old	NTR5119
Other	- : M014-024

Study results