De effectiviteit van het hepatitis B vaccin bij kinderen geboren uit moeders met een inflammatoire darmziekte die anti-TNF hebben gebruikt tijdens de zwangerschap

No registrations found.

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

Summary

ID

NL-OMON20411

Source
Nationaal Trial Register

Brief title
HEFFIC study

Health condition

Hepatitis B vaccine
Children born to IBD mothers
Inflammatory Bowel Disease
Anti-TNF

Sponsors and support

Primary sponsor: Erasmus University Medical Centre
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

anti-HBs levels 4 weeks after last inoculation for HBV

Secondary outcome

(if required) anti-HBs levels after HBV booster vaccine in case of primary non-immunity

Study description

Background summary

Some women with Inflammatory Bowel Disease (IBD) will require anti-TNF treatment during pregnancy. Anti-TNF actively crosses the placenta from the mother to the fetus, resulting in clinically significant anti-TNF levels in the child, detectable until 6 months of age. There is some evidence that adult patients treated with anti-TNF have inadequate response to the hepatitis B (HBV) vaccine, which leads to non-immunity. We propose to investigate the response to the HBV vaccine of children exposed to anti-TNF in utero.

Study objective

The hypothesis is that children who are exposed to anti-TNF during pregnancy, and who are subsequently born with significant anti-TNF levels detectable until at least 3 months of age, will insufficiently generate an adequate immune response (anti-HBs) to the hepatitis B vaccine.

Study design

venous blood sample will be drawn 4 weeks after the final inoculation for HBV (when the child is approximately 12 months old)

Intervention

-

Contacts

Public
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Scientific
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Eligibility criteria

Inclusion criteria

- Study group: children born to IBD mothers treated with anti-TNF (infliximab or adalimumab) during (part of) the pregnancy

- Control group: children born to IBD mothers not treated with anti-TNF (any other IBD medication)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- incapacity to understand the informed consent

- Maternal HBV, HCV or HIV infection

- Other immune-compromising conditions in the child

- Not intending to vaccinate child according to the Dutch National Vaccination Programme in Dutch: ‘Nederlandse Rijksvaccinatieprogramma’

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2014
Enrollment:	24
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-04-2014
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	NL4386
NTR-old	NTR4517
Other	NL47460.078.13 : MEC-2014-011

Study results

Summary results

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