Het natuurlijk beloop van inflammatoire darmziekten tijdens de zwangerschap

No registrations found.

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

Summary

ID

NL-OMON28895

Source
NTR

Brief title
PROPRE study

Health condition

Inflammatory bowel disease
Pregnancy
Gut microbiome

Sponsors and support

Primary sponsor: Erasmus Universit Medical Centre Rotterdam
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

- to analyze the gut microbiome of IBD patients during pregnancy; can the changes during pregnancy in the gut microbiome be linked to disease activity/flares.

Secondary outcome

- to analyze the effect of disease activity on pregnancy outcomes (gestational term, birth weight, congenital abnormalities, mode of delivery)

- to identify risk factors for an adverse disease course during pregnancy and adverse pregnancy outcomes

- to analyze the effect of different IBD medication use, independent of disease activity, during pregnancy on pregnancy course and outcomes

- to obtain data on the health of children born to IBD mothers (infections, allergies, growth) until 1 year and compare to children born to healthy mothers

Study description

Background summary

Crohn’s disease and ulcerative colitis, collectively referred to as inflammatory bowel disease (IBD), are chronic, relapsing diseases. The exact etiology remains unknown, however, it is currently believed to be a complex interaction between genetic susceptibility, gut microbiota, the host immune response and environmental factors(1). IBD typically arises at a young, fertile age, as 50% of patients will be younger than 35 years old when the diagnosis is established(2). Therefore, reproductive issues are of important concern for both the IBD patients and their treating physicians. Preconception counseling in these patients remains challenging, as many complex questions can only be answered with limited, mainly retrospective and sometimes conflicting data. In addition, most of the (registry based) cohorts are outdated(3-10), not including the most recent therapies for IBD like anti-TNF, which have become a mainstay in IBD treatment over the last decade(11). Obviously, the need for an up-to-date, properly conducted, prospective cohort is long overdue. We therefore propose to conduct a prospective cohort study in IBD females with a pregnancy wish and pregnant IBD females, to gather data on IBD characteristics during pregnancy and the effect of pregnancy on IBD. Furthermore, as a recent study has shown pregnancy to influence gut microbiota in non IBD patients(12), we also propose to investigate whether the gut microbiome in IBD patients changes during pregnancy and whether these changes have any clinical implications.

Study objective

The gut microbiome changes profoundly during pregnancy in healthy women. We hypothesize these microbiome changes will also occur in pregnant IBD women and can possibly have clinical implications.

Study design

Visit 1: before pregnancy (when patient expresses a pregnancy wish)

Visit 2: First trimester (gestational week 10)

Visit 3: Second trimester (gestational week 20)

Visit 4: Third trimester (gestational week 30)

1 year after delivery: retrospectively obtain health data on th child via General Practitioner

Intervention

No interventions

4 visits (1 before pregnancy, and 1 in each trimester) to obtain blood samples, fecal samples and questionnaires

Contacts

Public
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Eligibility criteria

Inclusion criteria

- Female

- Age 18-43

- Confirmed diagnosis of CD, UC or IBDu, by endoscopy and/or pathology

- Pregnancy wish

Exclusion criteria

- Incapacity to understand pre-conceptional counseling, informed consent and/or questionnaire (e.g. language barrier, no interpreter)

- Diabetes mellitus

- Infection with HIV, HBV or HCV

- Substance abuse (chronic hard drug use, alcoholism, shorter than 2 years clean)

- Other auto-immune diseases

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-04-2014
Enrollment:	270
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-04-2014

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	NL4426
NTR-old	NTR4550
Other	NL 47357.078.13 : MEC-2013-579

Study results