# Prospective follow up of the natural history of pregnant IBD patients

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

# **Summary**

### ID

NL-OMON26221

Source NTR

**Brief title** PROPRE

Health condition

inflammatory bowel disease

## **Sponsors and support**

**Primary sponsor:** Prof Dr MJ Bruno, Head of Gastroenterology and Hepatology Department, Erasmus MC, Rotterdam **Source(s) of monetary or material Support:** none

### Intervention

### **Outcome measures**

#### **Primary outcome**

- Gut microbiome changes over the course of pregnancy (before pregnancy, T1, T2 and T3 after delivery and and at least 3 months after delivery) in terms of diversity, taxonomic changes and richness

- Gut microbiome changes in children from IBD mothers in terms of diversity, taxonomic

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changes and richness compared to a historical cohort - Disease activity during pregnancy as measured by clinical activity scores (Harvey Bradshaw Index for CD and Simplified Clinical Colitis Activity Index), laboratory findings and/or endoscopy findings.

#### Secondary outcome

Birth outcomes Birth weight Gestational term Congenital abnormalities Mode of delivery APGAR scores at 1 minute and 5 minutes - Child health data: o Number of infections that required antibiotics o Hospital admissions o Growth o Reactions to vaccinations o Allergies

# **Study description**

#### **Background summary**

Prospective follow up of the natural history of pregnant IBD patients. In order to provide patients with appropriate pre-conceptional counseling regarding their disease in combination with pregnancy, more research needs to be done on this subject. We therefore aim to describe the natural history of IBD during and after pregnancy, investigate the gut microbiome at several time points during and after pregnancy and eventually assess the health and microbiome of the children born to IBD mothers in comparison to children of healthy mothers.

#### **Study objective**

Studies have described an altered bacterial diversity in the gut of women with IBD as compared to healthy controls. Infants born to mothers with IBD have shown to have lower diversity and altered gut microbiome at least until age 3 months. This might be important since prenatal and early life microbiome is thought to influence the development of the immune system. Whether this altered gut microbiome remains in women after pregnancy and in infants beyond age 3 months is unclear. We will perform follow up on the gut microbiome of women who previously in the study participated and their children beyond 3 months of age.

#### Study design

women: first, second and third trimester of pregnancy, after delivery and and at least 3 months after delivery children: at least 3 months after birth

#### Intervention

not applicable

# Contacts

#### Public

Haaglanden Medisch Centrum en ErasmusMC-Sophia kinderziekenhuis Jantien Bolt-Wieringa

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# **Eligibility criteria**

### **Inclusion criteria**

- Female
- Age 18-43
- Confirmed diagnosis of CD, UC or IBDu, by endoscopy and/or pathology

o For the retrospective part of the study:

□ Visited the pre-conception outpatient clinic after IBD diagnosis between January 2008 and December 2013 before pregnancy

□ Visited the pre-conception outpatient clinic after IBD diagnosis between January 2008 and December 2013 for the first time during pregnancy

- children of participating women

### **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:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

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Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	46
Туре:	Anticipated

### **IPD** sharing statement

Plan to share IPD: No

# **Ethics review**

Not applicable Application type:

Not applicable

# **Study registrations**

# Followed up by the following (possibly more current) registration

ID: 50661 Bron: ToetsingOnline Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL8418
ССМО	NL47357.078.13
OMON	NL-OMON50661

# **Study results**