Prospective follow up of the natural history of pregnant IBD patients

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26221

Bron
NTR

Verkorte titel
PROPRE

Aandoening

inflammatory bowel disease

Ondersteuning

Primaire sponsor: Prof Dr MJ Bruno, Head of Gastroenterology and Hepatology Department, Erasmus MC, Rotterdam
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

Publiek

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

088 979 7900

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2020
Aantal proefpersonen:	46
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50661
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten