Twin cohort for the study of (pre)clinical Inflammatory Bowel Disease in the Netherlands
The TWIN-study

No registrations found.

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

Summary

ID

NL-OMON23799

Source
NTR

Brief title
TWIN-IBD study

Health condition

Inflammatory Bowel Disease

IBD

M. Crohn

Crohn's disease

ziekte van Crohn

Ulcerative colitis

colitis ulcerosa

twin

tweeling

preklinisch

preclinical

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: This research is partially funded by a personal unrestricted grant from the Alexandre Suerman program for MD/PhD students of the University Medical Center Utrecht, the Netherlands.

Intervention

Outcome measures

Primary outcome

The association of the following factors with established and preclinical IBD will be studied:

- Environmental factors

- Early signs and symptoms of IBD development

- Immunological phenotyping and function

- Gut and oral microbiota anlayses

- Metabolome analyses

- Mucus barrier analyses

- Epithelium analyses

- DNA-sequencing analyses

Study description

Background summary

Inflammatory Bowel Diseases (IBD), i.e. Crohn’s Disease (CD) and Ulcerative Colitis (UC), are thought to arise in genetically susceptible individuals in the context of environmental

triggers, with a potential dominant role for the interplay between the gut microbiota, and the mucosal immune system. However, the relative importance and the exact role of these factors in the pathogenesis of IBD is presently unknown. Interpretation of published research in this field is often hampered by reverse causation, and data generated in animal models cannot be directly extrapolated to the human condition. The disease is probably triggered years before the occurrence of symptoms, but currently patients are only identified when clinical disease is established. The preclinical phase of IBD might hold the key to understanding the pathogenesis of IBD and could provide a huge window of opportunity of halting or even preventing disease development. At this time, data on this phase of the disease are virtually non-existent. What we do know is that unaffected twin-siblings of an IBD affected individual are at increased risk of developing IBD. Therefore, studying IBD-discordant, IBD-concordant and non-IBD-concordant twins or multiples gives the unique opportunity to 1) define mechanisms that underlie (the early development of) IBD and 2) identify markers of (pre)clinical IBD.

Study objective

Primary Objective: To gain insight in the disease mechanisms of IBD.

Secondary Objective(s): To identify biomarkers and study functional and mechanistic properties of the mucosal immune system, gut and oral microbiome, epithelium, mucus barrier, metabolome and nutritional factors in established and (pre)clinical IBD. Furthermore, we strive to identify symptoms and quality of life alterations associated with IBD.

Study design

Participants are invited for follow-up visits every 6 months during a period of 2 years. Afterwards the possible development of IBD will be assessed on a regular basis.

Intervention

This is an observational cohort study, designed to explore factors possibly contributing to the pathogenesis of Inflammatory Bowel Disease.

From all participants the following data will be collected:

- Demographics

- Disease history

- Medication history

- Current medication use

- Risk factors

- Family history

- Quality of life

- Food frequency questionnaires

From all participants the following samples will be collected:

- Feces

- Pharyngeal swabs

- Urine

- Blood

- Rectal biopsies

- Colonic or ileal biopsies (in case of a colonoscopy for a clinical indication)

Contacts

Public
kamernummer L00.418

Eelco Brand
Postbus 85500

Utrecht 3508 GA
The Netherlands
+31 88 755 9682
Scientific
kamernummer L00.418

Eelco Brand
Postbus 85500

Utrecht 3508 GA
The Netherlands
+31 88 755 9682

Eligibility criteria

Inclusion criteria

Inclusion criteria for IBD-discordant and IBD-concordant twins or multiples:

- Born as a sibling of, either a monozygous or dizygous, twin pair or multiplex

- One or more twin-siblings are affected with IBD, i.e. CD, UC or IBD unspecified (confirmed by clinical, endoscopic and histological features)

- Age: 16 years and older

Inclusion criteria for the unaffected controls (preferably twins or multiples):

- None of the siblings of the twin are affected with IBD, i.e. CD, UC or IBD unspecified

- Age: 16 years and older

Exclusion criteria

- No consent to participate in the study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-09-2017
Enrollment:	444
Type:	Anticipated

Ethics review

Positive opinion Date:	07-08-2017
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	NL6187
NTR-old	NTR6681
Other	METC van het UMC Utrecht : 17-333

Study results