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

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To gain insight in the disease mechanisms of IBD, the immune system, gut and oral microbiome, environmental factors, the intestinal mucus barrier, intestinal epithelium, nutritional factors and metabolome will be studied in unaffected siblings of...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON53107

Source
ToetsingOnline

Brief title
The TWIN study for Inflammatory Bowel Disease

Condition

- Gastrointestinal inflammatory conditions

Synonym
inflammatory bowel disease and Crohn's disease and Ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Maag-, Darm- en Leverziekten & Laboratorium voor Translationele Immunologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Crohn's disease, Inflammatory Bowel Disease (IBD), Twin, Ulcerative Colitis

Outcome measures

Primary outcome

Comparisons will be made between siblings of twin pairs and between IBD patients and non-IBD controls. Amongst others, changes in immune parameters in the mucosal and peripheral blood compartment, gut and oral microbiome, epithelium and mucus barrier function, and the metabolome will be studied. In addition, correlations between demographic, environmental and nutritional factors will be made, and quality of life an symptom fluctuations prior to or during IBD will be studied.

Secondary outcome

See above.

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 status 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 siblings of an IBD affected

individual are at increased risk of developing IBD. Therefore, studying IBD discordant twins gives the unique opportunity to 1) define mechanisms that underlie the early development of IBD and 2) identify markers of preclinical IBD.

Study objective

To gain insight in the disease mechanisms of IBD, the immune system, gut and oral microbiome, environmental factors, the intestinal mucus barrier, intestinal epithelium, nutritional factors and metabolome will be studied in unaffected siblings of IBD-affected individuals with a high risk of developing IBD compared with the IBD-affected twin individual, IBD-affected twin pairs, and healthy twin pairs.

Study design

Observational study with both a cross-sectional and longitudinal design. All participants will participate in the cross-sectional part, and a selection of participants will be followed over time.

Study burden and risks

At baseline, demographic factors and disease characteristics will be collected for all participants. The following parameters and biomaterials will be collected if specific informed consent is obtained: nutritional questionnaire data, environmental data, 60mL blood, faecal samples, pharyngeal swabs, urine samples, and rectal biopsies. If a patient agrees, the following will be collected around a colonoscopy for regular care: ileum, colon and rectal biopsies, as well as questionnaire data, blood, faecal, pharyngeal swabs and urine samples. A subgroup of participants will be followed-up at intervals of 6 months or one year for longitudinal studies. In these, the same parameters and biomaterials as at baseline will be collected. Rectal biopsies will be obtained only at yearly follow-up visits. If a participant consents and he/she still posesses deciduous teeth that they had changed in their childhood, we will also collect these deciduous teeth.
Due to the observational design of the study participants will not have direct benefit from participation. However insights gained from this cohort will increase our understanding from IBD, which can lead to improvement of care for IBD on the long-term. The blood withdrawal, urine sampling, pharyngeal swabs, and faecal sampling do not pose risks to participants. Biopsy taking carries a very low risk of bleeding or perforation of approximately 1 per 1000 colonoscopies. As we are performing only proctoscopies, we expect the risks of perforation and bleeding to be negligible. Furthermore, bowel preparation is not mandatory, rendering the procedure less burdensome for the participant. The risks of data and biomaterial collection during a colonoscopy for regular care do not increase risks that are already present because of the planned

colonoscopy.

Contacts

Public
Selecteer

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Selecteer

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria for the 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 or multiples are affected with IBD, i.e. CD, UC or IBD unspecified (self-reported diagnosis, to be confirmed during the study by clinical, endoscopic or histological reports from the treating physician)
- Age: 16 years and older, In order to be eligible to participate in this study, a subject must meet all of the following 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

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- No consent to participate in the study.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-09-2017
Enrollment:	444
Type:	Actual

Ethics review

Approved WMO

Date:	03-08-2017
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	18-05-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-07-2019
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-07-2022
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL61114.041.17