Molecular markers for diagnosis and therapy response in Inflammatory Bowel diseases: A prospective population based bio-bank of inflammatory bowel disease patients in Zuid Limburg, The Netherlands.

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Since a population based biobank with matched control subjects is the ideal study population for identification of causal pathways, the identification and confirmation of new molecular markers for disease course, phenotype and therapy response, we...

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

Summary

ID

NL-OMON50587

Source
ToetsingOnline

Brief title
A Prospective population based biobank for IBD in The Netherlands.

Condition

- Gastrointestinal inflammatory conditions

Synonym
inflammatory bowel disease

Research involving

Human

Sponsors and support

Primary sponsor: Interne geneeskunde/Divisie MDL
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biobank, Crohn's disease, Molecular Marker, Ulcerative colitis

Outcome measures

Primary outcome

niet van toepassing

Secondary outcome

niet van toepassing

Study description

Background summary

The invalidating inflammatory bowel diseases (IBD), Crohn*s disease (CD) and ulcerative colitis (UC) are characterized by a heterogenic clinical presentation and variable therapeutic response. A genetically altered intestinal immune response in interaction with environmental factors and intestinal microbiota are causing these diseases. Despite the identification of over 60 susceptibility genes trough large-scale genome wide association (GWA) studies and the identification of several serological markers, molecular diagnostics is still in its infancy. Currently, the diagnosis is accomplished via endoscopy and physician assessment, combined with non-molecular laboratory tests. Disease treatment consists of a succession of more or less successful therapeutic regimens, until one is selected as a reasonable balance between remediation of disease symptoms and side effects. Several IBD bio-banks are available world-wide but patients are collected in tertiary referral centers and therefore not representable for the IBD population. Furthermore disease phenotypes are mostly obtained by retrospective chart study. Since 1991 all the new IBD patients in South Limburg, The Netherlands were prospectively included in a disease registry due to collaboration of all the gastroenterologists of the 3 hospitals (Maastricht Universitair Medisch Centrum (MUMC), Maastricht, Atrium Medisch Centrum, Heerlen and Orbis MedischCentrum, Sittard-Geleen) in

the region. This project is further referred to as the IBD Zuid Limburg (IBD-ZL) cohort. Over 90% of IBD patients in the region are included in this project.

Study objective

Since a population based biobank with matched control subjects is the ideal study population for identification of causal pathways, the identification and confirmation of new molecular markers for disease course, phenotype and therapy response, we want to start a prospective population based IBD biobank of the existing IBD-ZL cohort.

Study design

Patients presently registered in the IBD-ZL cohort are described in table 1. The aim of this project is to start a bio-bank project of this cohort together with prospective data collection of disease phenotype, disease activity, response to treatment and disease course. Sufficient finances are available to include all IBD patients in the ZL registry in the biobank together with biomaterial of parents and partners serving as control subjects. All the patients in the registry will be contacted and be asked to participate. Patients will be visited at home by a genetic field worker. After giving their informed consent DNA, serum, plasma, exhaled air and a stool sample are collected. All the information obtained will be added to a specially designed web-base data management system (MACRO). The MACRO system guarantees safety and allows for direct inclusion of data in all the participating hospitals. Patient are assigned a number (family relations are detectable) and data is coded. Phenotypic information regarding disease location, behavior and complications will be extracted from the electronic patient files (EPD) in the participating centers and added to the MACRO database. An update of the disease phenotype will be performed every six months. Clinical information together with laboratory and endoscopic parameters of all the patients followed at the MUMC (one third of the patients) will be registered in MACRO prospectively at every patient visit in parallel with the Parel Snoer Initiative (PSI). Biomaterials are stored in the central biobank facility of the MUMC.

Study burden and risks

niet van toepassing

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inflammatory bowel disease patients of 18 years or older living in South-Limburg, The Netherlands. Patients should be competent to give consent. Partners living on the same address as the patient and parents of all the patients in the project., Addendum3, controls for GIS research question: Controls must be >18years, and their residence must be equally divided throughout South Limburg.

Exclusion criteria

IBD patients not living in South Limburg
Patients mentally incompetent
Patients under the age of 18

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):	15-03-2011
Enrollment:	5000
Type:	Actual

Ethics review

Approved WMO

Date:	02-03-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	07-06-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	09-09-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	12-11-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-06-2013
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-06-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-12-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-11-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-01-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL31636.068.10