

Risk Factors for Microscopic Colitis. A Dutch Case-Control Study

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

Summary

ID

NL-OMON45110

Source

ToetsingOnline

Brief title

Risk factors for MC

Condition

- Gastrointestinal inflammatory conditions

Synonym

Chronic colitis; lymphocytic colitis; collagenous colitis

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W, Dr. Falk Pharma Benelux BV

Intervention

Keyword: Epidemiology, Hygiene Hypothesis, Microscopic colitis, Risk Factors

Outcome measures

Primary outcome

The main study parameter is the assessment of environmental, hygiene-related risk factors for MC.

Secondary outcome

Secondary parameters are the difference between the CC and LC subpopulation regarding hygiene-related risk factors, living area as potential risk factor and the assessment of the more generally known risk factors (e.g. age, gender, smoking, medication).

A specific outcome is the risk of exposure to pollution in the living area, based on longitudinal residential data (GIS substudy).

Study description

Background summary

Microscopic colitis (MC) includes two main subtypes: lymphocytic colitis and collagenous colitis. MC is characterized by chronic, non-bloody, watery diarrhea and a normal appearing colonic mucosa, though with typical histological inflammatory changes. Although generally considered as a benign condition, MC has a chronic sustained course in the majority of patients and is associated with an impairment of health related quality of life.

Over the years several risk factors have been identified for MC. These were mainly generally known risk factors such as gender, age, comorbidities and smoking. Besides, some specific medicines, e.g. proton-pump inhibitors and NSAID*s, have also been found to increase the risk of MC. No research has ever been performed to identify environmental, hygiene-related risk factors for MC. In inflammatory bowel disease the hygiene hypothesis has gained interest. The

hypothesis states that a decreased antigenic exposure in childhood could be the cause of an immunological over-reaction at the time of a following microbial contact. In this light it would be interesting to investigate whether this hypothesis is also applicable to MC.

Study objective

The primary objective is to assess environmental, hygiene-related risk factors for MC. Secondary objectives are the difference between the CC and LC subpopulation regarding hygiene-related risk factors, living area as potential risk factor and the assessment of the more generally known risk factors (e.g. age, gender, smoking, medication).

Furthermore, the association between pollution in the living area and the risk of MC will specifically be addressed (GIS-substudy).

Study design

Case-control study

Study burden and risks

Neither patients nor controls will gain direct benefit from participation. The burden of the study mainly consist of the consumption of time and effort to fill out the questionnaire and to collect the swabs. There is no risk in completing the questionnaire. The risk of buccal swab collection is very low. The technique is easy and safe. Besides, a clear instruction about how to collect the material will be added.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients:

- diagnosed with microscopic/collagenous/lymphocytic colitis between 2000 and 2012; .
- inhabitant of Limburg / Eindhoven region at time of diagnosis.;
- Controls:
- never diagnosed with microscopic/collagenous/lymphocytic colitis;
- participant in 'IBD-ZL controlecohort'

Exclusion criteria

Patients + controls

- Age below 18 years at the time of diagnosis
- Not capable of signing an informed consent
- Deceased

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: Recruitment stopped

Start date (anticipated): 03-07-2014

Enrollment: 600

Type: Actual

Ethics review

Approved WMO

Date: 31-12-2013

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 07-12-2015

Application type: Amendment

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date: 18-04-2016

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

CCMO

ID

NL44127.068.13

Study results

Date completed: 19-07-2016

Actual enrolment: 637