A study on Intestinal Disease and Lifestyle - Disease characteristics and lifestyle factors in inflammatory bowel disease and irritable bowel syndrome

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At first, to describe the UC, CD, and IBS outpatient population in the Netherlands. Secondly to gain insight into disease and treatment characteristics, as well as lifestyle and clinical factors identified as potential risk factors of a UC, CD, and...

Ethical review Approved WMO

Status Pending

Health condition type Gastrointestinal inflammatory conditions

Study type Observational non invasive

Summary

ID

NL-OMON29893

Source

ToetsingOnline

Brief title

IDeaL study

Condition

Gastrointestinal inflammatory conditions

Synonym

chronic intestinal inflammation, inflammatory bowel disease

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

1 - A study on Intestinal Disease and Lifestyle - Disease characteristics and lifest ... 14-05-2025

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: IBD, IBS, lifestyle

Outcome measures

Primary outcome

- Disease characteristics; date of first complaints and diagnosis, date of last

complaints due to IBD and/or IBS and type of complaints, frequency of

complaints, and occurrence of extra-intestinal manifestations.

- Lifestyle characteristics; dietary intake, smoking behaviour, alcohol use,

stress, depression, anxiety, physical and sexual abuse.

Secondary outcome

- Clinical characteristics; measles vaccination or (perinatal) infection,

gastroenteritis, appendectomy, cholestectomy, hysterectomy, use of antibiotics,

and use of oral contraceptive and hormone replacement therapy (for women only),

family members with UC, CD, or IBS.

- Treatment characteristics; number of hospitalizations due to IBD or IBS,

number and kind of operations due to IBD, medication use including analgesic,

and Prednisone and Prednisolon.

Study description

Background summary

2 - A study on Intestinal Disease and Lifestyle - Disease characteristics and lifest ... 14-05-2025

Ulcerative colitis (UC) and Crohn*s disease (CD), both inflammatory bowel diseases (IBD), and irritable bowel syndrome (IBS) are common diagnoses in gastroenterology. Several factors may influence the development or course of IBD and IBS: lifestyle factors, like smoking, dietary intake including probiotic use, and psychosocial factors including stress, but also clinical factors like infection and vaccination, appendectomy, and use of oral contraceptives, analgesics, and antibiotics. Genetic factors might also influence the development and course of IBD and IBS. Unfortunately, causal relationships are hard to establish and a lot of controversies exist about underlying mechanisms. Our study is unique because it describes clinical factors as well as lifestyle factors, resulting in a broad overview of suggested factors for the development and course of IBD and IBS. Since IBD and IBS are studied simultaneously and with the same methods, comparisons can be made between the IBD and IBS population.

Study objective

At first, to describe the UC, CD, and IBS outpatient population in the Netherlands. Secondly to gain insight into disease and treatment characteristics, as well as lifestyle and clinical factors identified as potential risk factors of a UC, CD, and IBS outpatient population in the Netherlands. Thirdly, to search for associations between disease and treatment characteristics and (changes in) lifestyle and clinical factors. Finally, to assess the feasibility of a prospective cohort study with IBD and IBS outpatients.

Study design

Mono-centre cross-sectional study.

Study burden and risks

Participating in the IDeaL study means filling in a questionnaire about disease and treatment characteristics as well as lifestyle and clinical factors, and personal information. This will take approximately 30 minutes. There are no risks for the participants of this study.

Contacts

Public

Wageningen Universiteit

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- 1. Patients with Crohn's disease, ulcerative colitis, and/or irritable bowel syndrome.
- 2. Patients who visited a gastroenterologist at Gelderse Vallei Hospital in the last 10 years.
- 3. Patients aged 18 years and older.

Exclusion criteria

IBD and IBD patients who moved to a foreign country or when no address is available.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

4 - A study on Intestinal Disease and Lifestyle - Disease characteristics and lifest ... 14-05-2025

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2006

Enrollment: 1500

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

Review commission: METC Wageningen Universiteit (Wageningen)

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 NL11988.081.06