

# Causitive agents and risk factors of gastrointestinal infections in the general practitioners population (VERITHAS)

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The overall goal of this study is to get an up-to-date data on the incidence, disease burden, and etiology of gastrointestinal infections in the general practitioner population. More specific goals: 1. Determine the incidence of gastrointestinal...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal infections
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON49689

### Source

ToetsingOnline

### Brief title

Agents of gastroenteritis in the general practitioners population

### Condition

- Gastrointestinal infections
- Hepatobiliary neoplasms malignant and unspecified

### Synonym

gastroenteritis, gastrointestinal infections

### Research involving

Human

### Sponsors and support

**Primary sponsor:** RIVM

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

## Intervention

**Keyword:** epidemiology, etiology, gastroenteritis, microbiology

## Outcome measures

### Primary outcome

- Incidence of gastrointestinal infections in the general practitioner population and the general population per 1.000 person-years
- Prevalence per bacterial, viral and parasitic pathogen in persons visiting the general practitioner with a gastrointestinal infection, and the general population
- Risk factors for gastrointestinal infections, as well as pathogen-specific risk factors, in the general practitioner population and the general population
- Factors, such as severity of symptoms, that differentiate between persons for which diagnostic testing is requested by the general practitioner and those for which diagnostics is not requested

### Secondary outcome

Patients that gave consent to be approached again for future studies could provide insight in the development of sequelae following gastrointestinal infections. The feces databank provides opportunities for gut microbiome research.

## Study description

### Background summary

The last study on the etiology and epidemiology of gastro-intestinal infections in the general practitioners population was conducted in the 90s and is likely not representative for the current situation. However, it is still the basis for the NHG-standaard Acute diarrhea and burden estimations. Moreover, the diagnostics have changed substantially since the 90s.

## **Study objective**

The overall goal of this study is to get an up-to-date data on the incidence, disease burden, and etiology of gastrointestinal infections in the general practitioner population.

More specific goals:

1. Determine the incidence of gastrointestinal infections in the general population
2. Determine the proportion of gastrointestinal infections in the general population for which diagnostic testing is requested
3. Determine the incidence of multiple bacteria, viruses and parasites in persons visiting the general practitioner with a gastrointestinal infection, and compare it with the incidence in the general population
4. Determine (pathogen specific) risk factors that differentiate between persons with gastrointestinal infections for which diagnostic testing is requested by the general practitioner and those for which diagnostics is not requested

Optional:

5. Follow-up investigation on sequelae after gastrointestinal infections
6. Build a fecesbank for (future) pathogen discovery and microbiome research

## **Study design**

This is a prospective case-control study on gastro-intestinal infections in the general practitioners population. Patients visiting the general practitioner with a gastrointestinal infection and controls in the general population will be asked to collect two fecal samples for bacterial, viral and parasitic diagnostics. They are also asked to fill in a questionnaire containing questions about their household (e.g. number of persons), symptoms (type of symptoms, severity and duration), medicine use, sick leave, comorbidities and exposure (e.g. travelling abroad, animal contact).

## **Study burden and risks**

Participation is voluntary. Participants will be asked to fill two tubes with feces and complete a questionnaire. Filling in the questionnaire takes about 15 minutes. Patients in the general practitioners population can provide consent

to inform their general practitioners with the results of the diagnostics tests. It is possible that pathogens are found that can explain so far unexplained symptoms, providing the general practitioner with opportunities for treatment. The risk for participants is believed to be low, because participants only have to provide two fecal samples and complete a questionnaire. This application therefore requests exemption for test subject insurance application in the cover letter

## Contacts

### **Public**

RIVM

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### **Scientific**

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## Trial sites

### **Listed location countries**

Netherlands

## Eligibility criteria

### **Age**

Adolescents (12-15 years)

Adolescents (16-17 years)

Adults (18-64 years)

Children (2-11 years)

Elderly (65 years and older)

## Inclusion criteria

Patients:

Patients presenting at the general practitioners with the following ICPC codes:

- Diarrhea(ICPC code D11) with a suspected infectious cause
- Infectious diarrhea/dysenteriae (International Classification of Primary Care [ICPC] code D70)
- Presumed gastro-intestinal infection (ICPC code D73).

Controls:

Everyone who is registered in the population registry

## Exclusion criteria

Patients:

A person is excluded if he/she already adhered to the inclusion criteria in the three weeks before onset date OR if current complaints started more than 14 days ago

Controls:

There are no exclusion criteria

## Study design

### Design

Study type:	Observational non 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):	31-08-2020

Enrollment:	1000
Type:	Actual

## Ethics review

Approved WMO	
Date:	12-02-2020
Application type:	First submission
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	NL72240.041.19