

# Prevalence of Tropheryma whipplei in duodenum and colon, using real-time PCR

Published: 05-03-2008

Last updated: 10-05-2024

To determine the prevalence of T. whipplei in duodenum and colon in a random population of patients whom will undergo an endoscopy at the VUmc

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

## Summary

### ID

NL-OMON31715

### Source

ToetsingOnline

### Brief title

Prevalence of Tropheryma whipplei in the gut

### Condition

- Gastrointestinal infections

### Synonym

prevalence of T. whipplei, Whipple's disease

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

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

## Intervention

**Keyword:** gut, prevalence, real-time PCR, Tropheryma whipplei

## Outcome measures

### Primary outcome

Presence of T. whipplei DNA

### Secondary outcome

Quantitative determination of T. whipplei DNA

## Study description

### Background summary

Whipple's disease is a very rare infectious disease which can cause several intestinal and extraintestinal symptoms, varying from mild to very severe. The disease is caused by a specific bacteria, Tropheryma whipplei. It is difficult to cultivate the bacteria. Recently a very sensitive and specific real-time PCR has been developed which can reveal this bacteria. During a pilot study in 20 colonic mucosa biopsy specimens 3 specimens contained T.whipplei-DNA with use of real-time PCR. At this time nothing is known about the prevalence of T whipplei in the alimentary tract of humans.

### Study objective

To determine the prevalence of T. whipplei in duodenum and colon in a random population of patients whom will undergo an endoscopy at the VUmc

### Study design

Observational study

### Study burden and risks

Before endoscopy a questionnaire will be conducted. Height and weight of the patient will be measured.

During endoscopy two additional intestinal mucosa biopsy specimens will be harvested besides the usual specimens (normally 4 to 6).

## Contacts

### Public

Vrije Universiteit Medisch Centrum

De Boelelaan 1117  
1081HV Amsterdam  
Nederland

### Scientific

Vrije Universiteit Medisch Centrum

De Boelelaan 1117  
1081HV Amsterdam  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

18 years and older

Informed consent

Pre-endoscopy colonic cleansing with Kleanprep® (in case of colonoscopy)

### Exclusion criteria

Contraindication for endoscopy

Contraindication for harvesting biopsy specimens

Other pre-endoscopy colonic cleansing than with Kleanprep®

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-12-2008

Enrollment: 200

Type: Actual

## Ethics review

Approved WMO

Date: 05-03-2008

Application type: First submission

Review commission: METC Amsterdam UMC

## 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	NL21031.029.07