Helicobacter Pylori determination in a Fecal Immunochemical Test (FIT) - a proof of concept -

Published: 14-12-2017
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To evaluate the accuracy of H. pylori determination in FIT

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

Summary

ID

NL-OMON50384

Source
ToetsingOnline

Brief title
Helicobacter in FIT

Condition

- Gastrointestinal infections

Synonym
Campylobacter pyloridis, gastric bacterium

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: fecal immunochemical test, Helicobacter pylori, screening

Outcome measures

Primary outcome

1. PR, PPV/NPV, sensitivity and specificity of H. pylori determination in FIT,

compared to UBT

2. Differences in test performances before and after eradication therapy for

UBT, stool antigen assay (SAT) and FIT

Secondary outcome

1. PR, PPV/NPV, sensitivity and specificity of H. pylori determination in FIT

compared to SAT and serology

2. PR, PPV/NPV, sensitivity and specificity of SAT and serology, compared to

UBT

Study description

Background summary

Helicobacter pylori (H. pylori) is recognised as a worldwide problem. Asian countries are considered as high risk areas since the majority of the population is still infected with prevalence rates up to 80%. In low risk areas such as the Netherlands prevalence rate is decreasing and is stated around 30%. Risk factors for the acquisition of a H. pylori infection are low socioeconomic status, crowded living conditions and a lack of hot tap water. H. pylori is considered as the starting point of a sequence of several gastric conditions. This sequence leads from H. pylori infection to atrophic gastritis, intestinal metaplasia and dysplasia of the gastric mucosa and eventually ends in intestinal-type gastric adenocarcinoma in 1-2% of the infected patients. Over 80% of the patients with gastric cancer are infected by H. pylori. Usually, H. pylori infections do not resolve without eradication treatment (consisting of a combination of antibiotics and proton pump inhibitors). In current practice, it is recommended to eradicate this infection when identified. Indeed, some

studies even state to actively screen-and-treat patients with investigated dyspepsia.
The Consensus Group of the Asia-Pacific Consensus Guideline concluded a screen-and-treat method for H. pylori is a reasonable strategy in communities where the burden of gastric cancer is high. Although, they state major logistical issues need to be addressed for such a strategy to be widely adopted.There are several noninvasive tests available for the diagnosis of H. pylori infection, of which a stool antigen test (SAT) seems most suitable. This test could indicate an ongoing H. pylori infection and it is easy to perform. However, it is still on debate what type of stool sample is most eligible for the detection of H. pylori infections. Worldwide, screening programs for colorectal cancer (CRC) are already being implemented mostly by using fecal immunochemical tests (FIT). Eligibility of FIT for the diagnosis of H. pylori infection could lead to dual screening of the upper and lower gastrointestinal tract by using the same stool sample and overcome logistic barriers.

Study objective

To evaluate the accuracy of H. pylori determination in FIT

Study design

prospective, proof of concept study

Study burden and risks

No extra site visits are needed for this study. Patients are contacted by telephone one week prior to H. pylori testing. When willingness to participate, stool samples will be sent together with PIF/IC. On the day of the already planned UBT, stool samples will be collected and one blood sample will be drawn. Confirmation of eradication with repeated UBT is regular standard of care and will take place 4-6 weeks after antibiotic therapy. For study purposes, another 2 feces samples are asked to be collected. Burden and risks associated with participation is expected to be very low.
Gastroenterology staff will undergo the above mentioned tests because of their possible increased risk of having an H. pylori infection. As described, risks of undergoing these test are low. Participation in this study will provide insights in current H. pylori status for which treatment can be given in case of a positive test.

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

- Referred for an urea breath test via the outpatient clinic of the Erasmus MC, Albert Schweitzer Hospital or Maasstad Hospital
OR
- Staff working at the endoscopy department of the Erasmus MC and at risk for having a H. Pylori infection, such as gastroenterologists, endoscopy nurses, and laboratory assistants.

Exclusion criteria

Use of antibiotics/bismuth in the past 4 weeks
Use of PPI in the past 2 weeks

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2018
Enrollment:	284
Type:	Actual

Ethics review

Approved WMO Date:	14-12-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	26-08-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL62343.078.17