“Helicobacter pylori determination: Evaluation of Existing non-invasive methods and Linkage to Innovation” - The HELI-study -

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25263

Source
Nationaal Trial Register

Brief title
The HELI-study

Health condition

Helicobacter pylori, feces sample, urea breath test

Helicobacter pylori, fecestest, ademtest

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: Initiator = sponsor

Intervention

Outcome measures

Primary outcome

To compare the accuracy of H. pylori determination in FIT with golden standard UBT by assessing: Positivity Rate (PR), Positive Predictive Value (PPV), Negative Predictive Value (NPV), sensitivity and specificity

Secondary outcome

1. To compare the accuracy of H. pylori determination in FIT with SAT and serology by assessing PPV/NPV, sensitivity/specificity

2. To compare the accuracy of SAT and serology with UBT by assessing PPV/NPV, sensitivity/specificity

Study description

Background summary

Rationale

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%. 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 and eventually could end in gastric cancer in 1-2% of the infected patients. It is recommended to eradicate this infection when identified. In high-risk populations, a screen-and-treat method is even proposed. Although, 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 thereby overcome logistic barriers.

Objective: To evaluate the accuracy of H. pylori determination in FIT

Study design

Prospective, proof of concept study

Study population

All patients referred for an urea breath test (UBT) at the Erasmus MC

Intervention

Patients are simultaneously tested by means of UBT, serology, stool antigen assay (SAT), and FIT. Confirmation of eradication will be measured by UBT, SAT and FIT.

Main study parameters/endpoints

Main outcomes are PR, PPV/NPV, and sensitivity/specificity of H. pylori determination in FIT, SAT and serology, compared to UBT as the golden standard

Study objective

To compare non-invasive tests for H. pylori determination (serum, feces, breath test) within one subject with adding a novel feces sample: the fecal immunochemical test (FOB-Gold), used for colorectal cancer screening

Study design

Feces samples will be sent by mail after which feces collection can be done at home. These samples will be collected on the day of the urea breath test. During breath analysis a single blood sample will be drawn.

After inclusion of 85 patients an interim analysis will be performed. After complete inclusion all analyses will be performed.

Intervention

- 2x feces samples

- 1x vena punction

- 2x questionnaires

Contacts

Public
S.A.V. Nieuwenburg

Rotterdam
The Netherlands
Scientific
S.A.V. Nieuwenburg
Rotterdam
The Netherlands

Eligibility criteria

Inclusion criteria

- aged 18 years or older

- referred for urea breath test

Exclusion criteria

- Use of antibiotics/bismuth in the past 4 weeks

- Use of PPI in the past 2 weeks

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-02-2018

Enrollment:	184
Type:	Anticipated

Ethics review

Positive opinion Date:	07-02-2018
Application type:	First submission

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
NTR-new	NL6874
NTR-old	NTR7052
Other	METC Erasmus MC : MEC-2017-528

Study results