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

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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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25263

Bron
Nationaal Trial Register

Verkorte titel
The HELI-study

Aandoening

Helicobacter pylori, feces sample, urea breath test

Helicobacter pylori, fecestest, ademtest

Ondersteuning

Primaire sponsor: Erasmus Medical Center Rotterdam
Overige ondersteuning: Initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

- 2x feces samples

- 1x vena punction

- 2x questionnaires

Contactpersonen

Publiek

S.A.V. Nieuwenburg
Rotterdam
The Netherlands

Wetenschappelijk

S.A.V. Nieuwenburg
Rotterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- aged 18 years or older

- referred for urea breath test

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Use of antibiotics/bismuth in the past 4 weeks

- Use of PPI in the past 2 weeks

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart

(Verwachte) startdatum:	07-02-2018
Aantal proefpersonen:	184
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-02-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6874
NTR-old	NTR7052
Ander register	METC Erasmus MC : MEC-2017-528

Resultaten