The influence of a host genetic risk factor on H. pylori induced immune cell activation

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To assess the involvement of a specific genetic risk allele on oxidative stress induced by neutrophils in relation to H. pylori infection.

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

Summary

ID

NL-OMON36996

Source
ToetsingOnline

Brief title
H. pylori induced immune cell activation

Condition

- Gastrointestinal infections

Synonym
Helicobacter pylori, immunesystem

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: genetic risk factors, H. pylori, immune cell activation

Outcome measures

Primary outcome

The production of ROS by neutrophils related to the NCF4 mutation and H. pylori

status.

Secondary outcome

In H. pylori positive patients: CagA, VacA and OipA status. Pepsinogen I, II

and gastrin 17 level.

Study description

Background summary

Infection with H. pylori is still prevalent, especially in developing countries and ethnic minorities in Western urban areas. It can be the starting point for the development of serious diseases like duodenal ulcer and gastric adenocarcinoma. Until now, it is difficult to select patients with the highest risk for getting these diseases. We hypothesize that in people bearing a specific risk allele the production of ROS by neutrophils is impaired in response to H. pylori infection.

Study objective

To assess the involvement of a specific genetic risk allele on oxidative stress induced by neutrophils in relation to H. pylori infection.

Study design

Mono-center, laboratory study. Patients who are referred for a diagnostic urea breath test (UBT) to identify active H. pylori infection will be asked for consent for taking blood. Blood samples will be used to assess immune cell activity in relation to H. pylori and a host genetic risk factor.

Study burden and risks

After informed consent blood samples will be taken by vena puncture, the only extra procedure. Four tubes will be obtained once. Except a superficial hematoma, no risks are to be expected.

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

- Patients referred for Urea Breath Test (UBT)
- Age > 18 years
- Informed consent

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-11-2012
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	20-09-2012
Application type:	First submission
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	NL40866.078.12