Ammonia detection in Helicobacter pylori infections with the Ammonia Breath Analyzer (ABA) demonstrator. A pilot study to investigate the clinical application of the ABA.

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The aim of this study is to assess the change of ammonia exhaled in Helicobacter pylori (HP) positive patients compared with patients that are not HP infected after urea administration. In principle, in this pilot study, the results of Kearney et al...

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

Summary

ID

NL-OMON37532

Source
ToetsingOnline

Brief title
Ammonia detection in human breath in H. pylori infections

Condition

- Gastrointestinal infections

Synonym
dyspepsia, indigestion

Research involving
Human

Sponsors and support

Primary sponsor: SenzAir BV
Source(s) of monetary or material Support: SenzAir BV en subsidie uit "Pieken in de Delta;Oost Nederland;PIDON"

Intervention

Keyword: Ammonia, breath, Helicobacter pylori infection

Outcome measures

Primary outcome

The test variable is the concentration of the exhaled ammonia (ppm). Also the

respiratory ammonia output is determined (micro mol / min).

Secondary outcome

not applicable

Study description

Background summary

Breath Tests, which are applied in the diagnosis of Helicobacter pylori infection, all use the high urease activity of the micro-organism. The usual breath tests measure the increase in CO2 excretion in expired air after administration of 13C or 14C labeled urea. At the break-down of the urea, however, also NH4+ and NH3 in the gaseous phase are released. Only one study evaluated the measurement of this gas in exhaled air for the diagnosis of Helicobacter pylori infections in a small group of 13 subjects. Five of them were infected with Helicobacter pylori (according to a positive 14C-urea breath test).

Study objective

The aim of this study is to assess the change of ammonia exhaled in Helicobacter pylori (HP) positive patients compared with patients that are not HP infected after urea administration. In principle, in this pilot study, the results of Kearney et al (Dig Dis Sci 2002, 47:2523-2530) are objectified. This study showed that there was significant increase in ammonia exhalation from HP-infected (N = 5) patients after urea administration. The non-infected

individuals (N = 9) showed no increase

Study design

The test variable is the concentration of the exhaled ammonia (ppm). Also the respiratory ammonia output is determined (micro mol / min). Study design: In 30 HP+ and 30 HP non-infected infected patients these 2 variables are determined for one hour following the administration of 300 mg of urea at t = 0 and the administration of 500 mg Algeldraat at t = 30 minutes

Study burden and risks

The burden is very low. During the test the patients only have to breath into a mouthpiece. Also the risk of administration of urea and Algedraat is considered to be very low.

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 undergoing a diagnostic endoscopy which is based on their dyspeptic symptoms

Exclusion criteria

Patients using a proton pump blocker (PPI) within the preceding 14 days, or an antibiotic in the previous month are excluded from the study. Furthermore, patients are excluded if the extent of erosion of the tractus digestivus justifies immediate medical intervention.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-02-2013
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	20-11-2012

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL40399.091.12