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New Technology to Differentiate Normal Gastric Mucosa From Helicobacter Pylori Associated Gastritis and Gastric Atrophy

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ClinicalTrials.gov Identifier:

NCT02597517

[Recruitment Status](#) ⓘ : Completed[First Posted](#) ⓘ : November 5, 2015[Last Update Posted](#) ⓘ : May 3, 2016**Sponsor:**

Instituto Ecuatoriano de Enfermedades Digestivas

Information provided by (Responsible Party):

Instituto Ecuatoriano de Enfermedades Digestivas

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Study Description

Go to **Brief Summary:**

Endoscopy is a tool that has greatly influenced gastroenterological diagnosis. However, conventional endoscopy is limited to detecting lesions on the basis of gross morphological changes and therefore a certain diagnosis depends on biopsy sampling of macroscopically obvious endoscopic features, or blind biopsy sampling of normal appearing mucosa with the risk of missed pathology and sampling errors.

Gastric cancer is the second most common cause of cancer related death. One of the main roles of upper gastrointestinal endoscopy is to identify gastric cancer at an early stage. The importance of identifying H. pylori infection is because it plays a very important role in gastric carcinogenesis, progressing from chronic gastritis through atrophic gastritis, intestinal metaplasia, dysplasia and finally cancer. The importance of recognition a precancerous gastric lesion is because we can detect most tumors at an early stage and improve the survival.

Most studies conclude that it is difficult to diagnose H. pylori related gastritis and gastric atrophy on the basis of endoscopic findings. Histology is therefore currently considered to be the gold standard for detecting H. pylori infection. The reliability of detecting H. pylori infection histologically depends on the site, number, and size of gastric biopsy specimens, as well as on expertise in staining and visualizing the bacteria. Considerable error also occurs in identifying gastric atrophy using blind biopsy sampling, and neither the original nor the revised version of the Sydney system reliably identifies more than half the cases in patients with confirmed gastric atrophy.

<u>Condition or disease</u> ⓘ	<u>Intervention/treatment</u> ⓘ
Gastritis Helicobacter Pylori Associated Gastritis Atrophic Gastritis	Device: Digital chromoendoscopy and magnification



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Study Design

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Study Type ⓘ : Observational

Actual Enrollment ⓘ : 72 participants

Observational Model: Case Control

Time Perspective: Cross-Sectional

Official Title: Optical Enhancement System [™] Plus Optical Magnification Utility in the Identification of Normal Gastric Mucosa, Helicobacter Pylori Associated Gastritis, and Gastric Atrophy

Study Start Date ⓘ : November 2015

Actual Primary Completion Date ⓘ : April 2016

Actual Study Completion Date ⓘ : May 2016

Groups and Cohorts

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<u>Group/Cohort</u> ⓘ	<u>Intervention/treatment</u> ⓘ
Intervention group (Digital chromoendoscopy and magnification) Patients with functional dyspepsia and positive stool antigen test for H pylori in whom gastric body mucosal will be evaluated with digital chromoendoscopy (OE system) and magnification technology in addition to white light	Device: Digital chromoendoscopy and magnification After the gastric body mucosal evaluation with white light endoscopy, the Optical Enhancement chromoendoscopy and magnification will be used for a more detailed evaluation of the subepithelial capillary network, the collecting venules and mucosal pits Other Name: OE System (EPK-i7010) and Magniview (EG-2990Zi)

Control group

(Digital chromoendoscopy and magnification)

Patients with functional dyspepsia and negative stool antigen test for H pylori in whom gastric mucosal body will be evaluated with digital chromoendoscopy (OE system) and magnification technology in addition to white light

Device: Digital chromoendoscopy and magnification

After the gastric body mucosal evaluation with white light endoscopy, the Optical Enhancement chromoendoscopy and magnification will be used for a more detailed evaluation of the subepithelial capillary network, the collecting venules and mucosal pits

Other Name: OE System (EPK-i7010) and Magniview (EG-2990Zi)

Outcome Measures

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Primary Outcome Measures :

1. Utility OE System™ + Magniview™ in the diagnosis of normal gastric mucosa. Number of patients with type 1 in the Anagnostopoulos GK et al. classification. [Time Frame: two months]

Anagnostopoulos GK et al. classified the gastric body mucosal in four types: type 1, honeycomb-type subepithelial capillary network (SECN) with regular arrangement of collecting venules and regular, round pits. Type 1 pattern for predicting normal gastric mucosa.

2. Utility OE System™ + Magniview™ in the diagnosis of Helicobacter pylori associated gastritis. Number of patients with type 2,3 in the Anagnostopoulos GK et al. classification. [Time Frame: two months]

Anagnostopoulos GK et al. classified the gastric body mucosal in four types: type 2, honeycomb-type SECN with regular, round pits, but loss of collecting venules; type 3, loss of normal SECN and collecting venules, with enlarged white pits surrounded by erythema. Types 2 and 3 patterns for predicting a Helicobacter pylori infection.

3. Utility OE System™ + Magniview™ in the diagnosis of gastric atrophy. Number of patients with type 4 in the Anagnostopoulos GK et al. classification. [Time Frame: two months]

Anagnostopoulos GK et al. classified the gastric body mucosal in four types: type 4, loss of normal SECN and round pits, with irregular arrangement of collecting venules. Type 4 patterns for predicting gastric atrophy.

Secondary Outcome Measures :

1. Measures inter and intra-observer reproducibility in the assessment of the endoscopic patterns detected. [Time Frame: two months]


A data set containing photographs of the gastric lesions will be presented to three blinded endoscopists who will confirm or not the findings. Inter and intra-observer reproducibility will be measured based on

comparison of still images between the three investigators. To evaluate the intra-observer agreement each investigator will assess the images three times and the answers will be compared. To evaluate the inter-observer agreement all answers between the three investigators will be compared. To examine inter and intra observer agreement, kappa values will be calculated.

Biospecimen Retention: Samples Without DNA

Histological biopsies from gastric mucosal

Eligibility Criteria

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Information from the National Library of Medicine



Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, [Learn About Clinical Studies](#).

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Sampling Method: Probability Sample

Study Population

Two groups of functional dyspeptic patients will be selected randomly. Functional dyspepsia will be considered according to the Rome III. Criteria. It will include Epigastric pain Syndrome defined as located pain or burning in the upper abdomen, at least once a week, intermittent, not generalized, not relieved by defecation and without criteria of gall bladder or sphincter of Oddi pathology; and Postprandial distress Syndrome defined as the presence of one or both conditions including nagging feeling of postprandial fullness after normal volume meals, several times a week and early satiety that prevents the completion of a regular meal, several times a week. The criteria must be present in the last three months and have started at least 6 months before diagnosis.

Criteria

Inclusion Criteria:

- Above 18 years old patients
- Who agree to participate in the study
- Patients with functional dyspeptic symptoms

Exclusion Criteria:

- Patients, who were receiving nonsteroidal anti-inflammatory drugs, pump inhibitors (PPI) or antibiotics in the last 3 weeks.
- Severe uncontrolled coagulopathy
- Prior history of gastric surgery.
- Pregnancy and lactation

Contacts and Locations

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Information from the National Library of Medicine



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Please refer to this study by its ClinicalTrials.gov identifier (NCT number):
NCT02597517

Locations

Ecuador

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Sponsors and Collaborators

Instituto Ecuatoriano de Enfermedades Digestivas

Investigators

Principal Investigator: Carlos A Robles-Medranda, MD Ecuadorian Institute of Digestive Diseases

More Information

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Publications of Results:

[Anagnostopoulos GK, Yao K, Kaye P, Fogden E, Fortun P, Shonde A, Foley S, Sunil S, Atherton JJ, Hawkey C, Ragunath K. High-resolution magnification endoscopy can reliably identify normal gastric mucosa, Helicobacter pylori-associated gastritis, and gastric atrophy. Endoscopy. 2007 Mar;39\(3\):202-7. Epub 2007 Feb 1.](#)

[Correa P. Human gastric carcinogenesis: a multistep and multifactorial process--First American Cancer Society Award Lecture on Cancer Epidemiology and Prevention. Cancer Res. 1992 Dec 15;52\(24\):6735-40. Review.](#)

[Whiting JL, Sigurdsson A, Rowlands DC, Hallissey MT, Fielding JW. The long term results of endoscopic surveillance of premalignant gastric lesions. Gut. 2002 Mar;50\(3\):378-81.](#)

[Bah A, Saraga E, Armstrong D, Vouillamoz D, Dorta G, Duroux P, Weber B, Froehlich F, Blum AL, Schnegg JF. Endoscopic features of Helicobacter pylori-related gastritis. Endoscopy. 1995 Oct;27\(8\):593-6.](#)

[Calabrese C, Di Febo G, Brandi G, Morselli-Labate AM, Areni A, Scialpi C, Biasco G, Miglioli M. Correlation between endoscopic features of gastric antrum, histology and Helicobacter pylori infection in adults. Ital J Gastroenterol Hepatol. 1999 Jun-Jul;31\(5\):359-65.](#)

[Dixon MF, Genta RM, Yardley JH, Correa P. Classification and grading of gastritis. The updated Sydney System. International Workshop on the Histopathology of Gastritis, Houston 1994. Am J Surg Pathol. 1996 Oct;20\(10\):1161-81. Review.](#)

[Neumann H, Fujishiro M, Wilcox CM, Mönkemüller K. Present and future perspectives of virtual chromoendoscopy with i-scan and optical enhancement technology. Dig Endosc. 2014 Jan;26 Suppl 1:43-51. doi: 10.1111/den.12190. Epub 2013 Oct 23. Review.](#)

[Drossman DA. The functional gastrointestinal disorders and the Rome III process. Gastroenterology. 2006 Apr;130\(5\):1377-90. Review.](#)

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gastritis
chromoendoscopy
magnification
Helicobacter pylori
Atrophic gastritis

Additional relevant MeSH terms:

Atrophy	Gastroenteritis
Gastritis	Gastrointestinal Diseases
Gastritis, Atrophic	Digestive System Diseases
Pathological Conditions, Anatomical	Stomach Diseases