

Specific contributors for the development of intestinal metaplasia of the cardia

Submission date 22/01/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/02/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/02/2010	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
001

Study information

Scientific Title

Age, smoking and weight are main contributors for the development of intestinal metaplasia of the cardia

Study objectives

The aim of this study was to assess the respective roles of *Helicobacter pylori* (HP), gastroesophageal reflux, age, smoking habit and obesity on the development of intestinal metaplasia of the cardia (IMC)

Ethics approval required

Old ethics approval format

Ethics approval(s)

In 2003, at the start of this study no Ethical commission existed. The study design was approved by the head of University Hospital Geneva and University Hospital Lausanne, where the patients were recruited.

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied

Intestinal metaplasia of the cardia (IMC)

Interventions

217 patients were studied. The appointment letter was sent to the patient with the written information leaflet usually within one week before endoscopy. Patient consent to participate was obtained only upon his/her arrival for the endoscopic procedure. Therefore, all patients signed an informed consent form upon their arrival.

Gastroesophageal Reflux Disease (GERD), smoking habit, body mass index (BMI) and age were recorded. Biopsies were histologically evaluated for specialised intestinal metaplasia.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Assessment of the respective roles of HP, GERD, age, smoking habit and obesity on the development of IMC

Secondary outcome measures

none

Overall study start date

01/01/2001

Completion date

31/12/2004

Eligibility**Key inclusion criteria**

1. All patients scheduled for an elective digestive endoscopy (upper gastrointestinal endoscopy) over a 3 year period allowing us to include at least 200 patients.
2. Living in Switzerland and can understand French
3. Outpatients only
4. Written informed consent

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200 (217 at final recruitment)

Key exclusion criteria

1. Age < 18 years
2. Pregnancy
3. Patients unable to give their own consent
4. Patients that had already undergone prior endoscopy
5. Previous history of upper-digestive surgery
6. Severe bleeding diathesis (platelet count <50,000/mm³)
7. Prothrombin rate <50%)
8. Psychiatric diseases
9. Allergy to lidocaine

Date of first enrolment

01/01/2001

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

Switzerland

Study participating centre

Division of Gastroenterology,

Geneva

Switzerland

1211

Sponsor information

Organisation

Geneva University Hospital (Switzerland)

Sponsor details

Rue Micheli du Crest

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1211

+41 (0)22 3729346

jean-louis.frossard@hcuge.ch

Sponsor type

Hospital/treatment centre

Website

<http://www.hcuge.ch>

ROR

<https://ror.org/01m1pv723>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Geneva University Hospital (Switzerland)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration