ISRCTN12753474 https://doi.org/10.1186/ISRCTN12753474

Risk study of pre-neoplastic lesions in the low esophagus

Submission date
20/01/2019

Recruitment status
No longer recruiting

Registration date
13/02/2019

Overall study status
Completed

Last Edited
11/02/2019

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Barrett's esophagus is an acquired condition that predisposes to the development of esophageal adenocarcinoma. The main objective of this research was to establish an association between the endoscopic and the histopathological findings regarding differently sized endoscopic columnar epithelial mucosa projections in the low esophagus, under 3.0 centimeters in longitudinal extent.

Who can participate?
All patients coming in with a request for upper gastrointestinal endoscopy, regardless of the clinical indication.

What does the study involve?
Upper gastrointestinal endoscopy followed by a biopsy.

What are the possible benefits and risks of participating?
The benefits and risks of participating are the same of gastrointestinal endoscopy.

Where is the study run from?
Clínica Cirúrgica do Aparelho Digestivo, Clínica de Endoscopia do Hospital Casa de Saúde and Serviço de Endoscopia da Unidade de Cirurgia Digestiva do Hospital Universitário de Santa Maria, in Santa Maria, RS, Brazil

When is the study starting and how long is it expected to run for?
July 2015 to June 2017.

Who is funding the study?
Hospital Universitário de Santa Maria and investigator initiated and funded.

Who is the main contact?
Hairton Copetti
hairtoncopetti@gmail.com

Contact information

Type(s)
Public

Contact name
Mr Hairton Copetti

Contact details
Av. Presidente Vargas 2355 - Policlínica Provedor Wilson Aita
Sala 1307 - 13º Andar
Santa Maria
Brazil
97015-513

Additional identifiers

Protocol serial number
1.008.491

Study information

Scientific Title
Risk study of pre-neoplastic lesions in differently-sized mucosa projections of columnar epithelium in the low esophagus

Study objectives
Establish an association between the endoscopic and the histopathological findings regarding differently sized endoscopic columnar epithelial mucosa projections in the low esophagus, under 3.0 centimeters in longitudinal extent

Ethics approval required
Old ethics approval format

Ethics approval(s)
Instituto Universitário Italiano de Rosário's Bioethics Committee, 28/06/2016, ref. nro. 04/16.

Study design
Prospective, experimental study, of diagnostic investigation, by a series of consecutive cases in three different locations

Primary study design
Other

Study type(s)
Screening

Health condition(s) or problem(s) studied
Progression of Barrett's esophagus to adenocarcinoma

Interventions
All consecutive patients coming in with a request for upper gastrointestinal endoscopy were included, regardless of the clinical indication, between April/2015 and August/2016.

In performing the exams, habitual technique for upper gastrointestinal endoscopies was followed: suspicious areas were identified by mucosa projection, from the top of the gastric folds to the columnar mucosa, more reddish and vascularized in the low esophagus. At this moment, insufflation was diminished for better identification of the gastric folds. Then, a 1.5% application of acetic acid was used for coloring. Once the suspicious area was identified, a previously laser-graded biopsy clamp with 0.5 cm intervals, designed by the author, was introduced through the gastroscope working canal; the projection was measured and then biopsies were performed following the Seattle Protocol (Figs. 3, 4, 5, 6 and 7).

The observation time was during the exam. There was no follow-up.

Intervention Type
Device

Primary outcome(s)
Diagnosis of Barrett's esophagus was determined using upper gastrointestinal endoscopy to detect the presence of columnar mucosa in the esophagus in the shape of digitiform projections, or segments that cover the circumference of the esophagus partially or totally.

Key secondary outcome(s))
1. The number of suspected lesions was determined using upper gastrointestinal endoscopy.
2. The size of suspected lesions was measured using previously laser-graded biopsy clamp with 0.5cm intervals, designed by the author, and divided in three groups of interes: Group 1 - projections up to 0.99cm, group 2 - 1.00 to 1.99cm and group 3 - 2.00 to 2.99cm, and then biopsied following the Seattle Protocol.
3. The number of suspected lesions during endoscopic examination was 81, where 59 subjects (72.8%) did not confirm for Barrett's esophagus after histologic exam, and 22 (27.2%) were confirmed, representing 1.74% of sample total

Completion date
30/07/2017

Eligibility

Key inclusion criteria
Request for upper gastrointestinal endoscopy

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Oesophageal obstruction
2. Post-oesophagectomy and bariatric surgery patients
3. Projections ≥3cm
4. Patients under 18 years of age

Date of first enrolment
01/06/2015

Date of final enrolment
30/08/2016

Locations

Countries of recruitment
Brazil

Study participating centre
Clínica Cirúrgica do Aparelho Digestivo
Av. Presidente Vargas 2355 - Policlínica Provedor Wilson Aita
Sala 1307 - 13º Andar
Santa Maria
Brazil
97015-513

Study participating centre
Clínica de Endoscopia do Hospital Casa de Saúde
Rua Ary Lagranha Domingues, 188 - Perpétuo Socorro
Santa Maria
Brazil
97045-060

Study participating centre
Serviço de Endoscopia da Unidade de Cirurgia Digestiva do Hospital Universitário de Santa Maria
Av. Roraima 1000, Prédio 22, Campus, Bairro Camobi
Santa Maria
Brazil
97105-900

Sponsor information

Organisation
Hospital Universitário de Santa Maria

ROR
https://ror.org/00aqfrr40

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Investigator initiated and funded

Funder Name
Hospital Universitário de Santa Maria

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Hairton Copetti, hairtoncopetti@gmail.com, the files will be stored in a personal computer, in the researcher's office, protected by password, only avaliable upon request, and will be shared according to the terms of our consent from participants. The files will be stored for five years.

IPD sharing plan summary
Available on request