

Risk study of pre-neoplastic lesions in the low esophagus

Submission date 20/01/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/02/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/02/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
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Contact information

Type(s)

Public

Contact name

Mr Hairton Copetti

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Study setting(s)

GP practice

Study type(s)

Screening

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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.

Secondary outcome measures

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 interest: 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

Overall study start date

10/04/2015

Completion date

30/07/2017

Eligibility

Key inclusion criteria

Request for upper gastrointestinal endoscopy

Participant type(s)

Other

Age group

All

Sex

Both

Target number of participants

At least 1000

Key exclusion criteria

1. Oesophageal obstruction
2. Post-oesophagectomy and bariatric surgery patients
3. Projections ≥ 3 cm
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

Sponsor details
Gabinete de Ensino e Pesquisa
Av. Roraima nº 1000, Prédio 22
Térreo, próximo a Superintendência
Bairro Camobi, Cidade Universitária
Santa Maria
Brazil
97105-900

Sponsor type
University/education

Website
<http://coral.ufsm.br/depe/>

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

Publication and dissemination plan

I want to publish my research papers in Journal of Gastroenterology as soon as possible

Intention to publish date

05/04/2019

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 available 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