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How to handle endoscopic mucosal resection specimens: randomised controlled trial to compare three different specimen handling methods.

Submission date
04/04/2018

Registration date
23/04/2018

Last Edited
01/04/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Barrett's esophagus is a condition of the lower part of the esophagus (food pipe). Repeated damage, caused by backflowing stomach acid over many years, can eventually cause changes in the cells that line the esophagus. These abnormal cells are at an increased risk of abnormal growth of tissue (known as neoplasia) and might become cancerous. Endoscopic resection (ER) is a procedure to remove abnormal tissue in Barrett's esophagus. However, accurate evaluation of an ER tissue sample (specimen) under the microscope can be challenging. The preferred method for handling of ER specimens remains unknown.
Therefore the aim of this study is to compare three different methods of specimen handling for adequate evaluation of all factors, and time required for handling.

Who can participate?
Adults with Barrett's esophagus related neoplasia

What does the study involve?
ER specimens collected from participants are randomly allocated to one of three methods of specimen handling. There is no further follow up with participants.

What are the possible benefits and risks of participating?
There are no benefits or risks for the participant.

Where is the study run from?
1. St. Antonius Hospital Nieuwegein (Netherlands)
2. Academic Medical Center Amsterdam (Netherlands)
3. Catharina Hospital Eindhoven (Netherlands)

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

Who is funding the study?
St. Antonius Research Fund (Netherlands)

Who is the main contact?
1. Dr. A. Overwater (Public)
2. Prof. B.L.A.M. Weusten (Scientific)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

15.0209

Study information

Scientific Title
New pathology box for specimen preparation after EMR: a randomized controlled trial of three different ways of specimen handling (the Cassette study)

Acronym
n/a

Study objectives
The aim of this study is to compare three different methods of specimen handling for:
1) enabling adequate evaluation of all clinically relevant histologic parameters of endoscopic resection specimens with no suspicion of submucosal invasion
2) required time for specimen handling

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval not required: The Medical Ethics Review Committee of the Academic Medical Center Amsterdam evaluated the study protocol and stated that the Medical Research Involving Human Subjects Act (WMO) does not apply to this study, ref: W15_172 # 15.0209

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Barrett's esophagus related neoplasia

Interventions
Specimens are collected from participants with Barrett's Esophagus related neoplasia that have an endoscopic resection. They are randomly allocated to one of three different methods of specimen handling:

1. Pinning on paraffin: The pinning method comprises smooth stretching of the endoscopic mucosal resection (EMR) specimen and pinning it out on cork or paraffin.
2. Cassette technique: The cassette (Boston Scientific, Marlborough, U.S.A.) is a small box in which an EMR specimen can be enclosed after stretching it out on paper. By closing the cassette, gentle pressure is applied on the specimen during the process of formalin fixation to prevent curling of the lateral margins of the resection specimen.
3. Direct fixation in formalin: Direct fixation of the EMR specimen in formalin with no prior handling.

Intervention Type
Other

Primary outcome measure
The overall ability to assess all relevant histopathological parameters is assessed using a 5-point Likert scale during central revision by 2 blinded Barrett's esophagus (BE) expert pathologists after inclusion of all EMR specimens is completed and all primary histopathologic evaluations in the treating centers are finished

Secondary outcome measures
1. The ability to adequately assess the vertical and lateral resection margins, tumor differentiation grade, tumor infiltration depth and lymphovascular invasion is assessed using a 5-point Likert scale during central revision by 2 blinded Barrett's esophagus (BE) expert pathologists after inclusion of all EMR specimens is completed and all primary histopathologic evaluations in the treating centers are finished.
2. Time necessary for handling of the endoscopic resected specimen measured in seconds directly after the endoscopic resection is completed.

Overall study start date
27/09/2015

Completion date
01/06/2017

Eligibility

Key inclusion criteria
1. Endoscopic resection specimens of Barrett's esophagus related neoplasia
2. No suspicion of submucosal invasion acquired by Multi-band mucosectomy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
120 endoscopic mucosal resection specimens

Key exclusion criteria
1. Poor tumor differentiation grade (if known beforehand)
2. Suspicion of submucosal invasion during endoscopy

Date of first enrolment
01/01/2016

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
St. Antonius Hospital
Koekoekslaan 1
Nieuwegein
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Study participating centre
Academic Medical Center
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Study participating centre
Catharina Hospital Eindhoven
Michelangelolaan 2
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5623 EJ

Sponsor information

Organisation
St. Antonius Hospital Nieuwegein

Sponsor details
Koekoekslaan 1
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01jvpb595

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
St. Antonius Research Fund

Results and Publications

Publication and dissemination plan
Planned submission of manuscript to a high-impact peer reviewed journal.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from B.L.A.M. Weusten, b.weusten@antoniusziekenhuis.nl

Additional documentation:
Full trial protocol is available upon request by the principle investigator as above.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2019		Yes	No