ISRCTN68328077 https://doi.org/10.1186/ISRCTN68328077

Endoscopic Tri-Modal Imaging for the detection of early neoplasia in patients with Barrett's oesophagus in tertiary referral Centres: a randomised cross-over multicentre study

Submission date
30/05/2007

Recruitment status
No longer recruiting

Registration date
30/05/2007

Overall study status
Completed

Last Edited
05/11/2010

Condition category
Cancer

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jacques Bergman

Contact details
Academic Medical Centre (AMC)
Department of Gastroenterology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5663556
j.j.bergman@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
ETMIC

Study objectives
Endoscopic Tri-Modal Imaging (ETMI) improves the detection of early neoplasia in Barrett's oEsophagus (BE).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethical Commission of the Academic Medical Centre on the 18th January 2007 (ref: MEC 06/292).

Study design
Randomised, active controlled, multicentre, crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Health condition(s) or problem(s) studied
Barrett's oesophagus, autofluorescence imaging, narrow band imaging

Interventions
In this study we will compare diagnostic endoscopy techniques for the detection of early neoplasia in Barrett's oesophagus. These techniques are Standard Video Endoscopy (SVE) (the current standard) and Endoscopic Tri-Modal Imaging (ETMI).

Patients will undergo two consecutive endoscopies in an interval of 8 to 12 weeks. One of the two aforementioned techniques will be randomly assigned to the first procedure; the second procedure will subsequently be performed with the other technique by a second endoscopist.

The primary outcome will be the number of lesions and patients with early neoplasia detected with standard video endoscopy and ETMI.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The number of patients and the number of lesions with early neoplasia detected with SVE and ETMI
2. The number of patients with early neoplasia detected with targeted biopsies only with ETMI and SVE

Secondary outcome measures
1. The sensitivity and Positive Predictive Value (PPV) of High-Resolution Endoscopy (HRE) and Autofluorescence Imaging (AFI)
2. The reduction of false positive findings after Narrow Band Imaging (NBI)
3. Negative predictive value of the combination of HRE and AFI and the reduction in false negative findings after

Overall study start date
01/03/2007

Completion date
01/09/2008

Eligibility

Key inclusion criteria
1. Aged greater than 18 years
2. Prior diagnosis of BE defined as the presence of columnar lined epithelium in the tubular oesophagus with specialised intestinal metaplasia on histological investigation
3. Prior diagnosis of high-grade dysplasia or early cancer that was endoscopically inconspicuous according to the referring physician. Review of the pathology slides is not required for inclusion
4. A minimum Barrett's length of C greater than 2M greater than 2 or C less than 2M greater than 4 according to the Prague C&M classification of the endoscopic appearance of BE
5. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
84

Key exclusion criteria
1. Presence of active erosive oesophagitis greater than grade A according to the Los Angles classification of erosive oesophagitis
2. Description of an endoscopically visible suspicious lesion in the Barrett's segment in the referring centre
3. Presence of conditions precluding histological sampling of the oesophagus (e.g. oesophageal varices, coagulation disorders, anticoagulant therapy)

Date of first enrolment
01/03/2007

Date of final enrolment
01/09/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details
Department of Hepato- and Gastro-enterology
P.O. Box 22660
Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl/index.cfm?sid=818

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Industry

Funder Name
Olympus Corporation (Japan)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2007		Yes	No
Results article	results	01/10/2010		Yes	No