

Endoscopic Tri-Modal Imaging versus standard video endoscopy for the detection of early neoplasia in patients with low-grade dysplasia in a Barrett's oesophagus: a multicentre randomised cross-over controlled study

Submission date 01/02/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 01/02/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/07/2011	Condition category Digestive System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Acronym

GETMI

Study objectives

Endoscopic Tri-Modal Imaging (ETMI) increases the detection rate of early neoplasia in Barrett's oesophagus (BE) patients with 40% or more compared to Standard Video Endoscopy (SVE).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local medical ethics committee on the 10th August 2006 (ref: MEC 05 /068).

Primary study design

Interventional

Study design

Randomised, crossover multicentre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Barrett's oesophagus

Interventions

ETMI-gastroscopy and standard video gastroscopy

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Number of patients with early neoplasia detected with ETMI or SVE
2. Number of lesions with early neoplasia detected with ETMI and SVE

Key secondary outcome(s)

1. Number of early neoplastic lesions detected with AutoFluorescence Imaging (AFI) only
2. Reduction of false positives findings after detailed Narrow Band Imaging (NBI) evaluation

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Barrett's oesophagus patients with low-grade dysplasia confirmed by two expert GastroIntestinal (GI) pathologists
2. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

1. Presence of active erosive oesophagitis grade A according to the Los Angeles classification of erosive oesophagitis
2. Presence of conditions precluding histological sampling of the oesophagus (e.g. oesophageal varices, coagulation disorders, anticoagulant therapy)
3. Less than 18 years

Date of first enrolment

01/01/2007

Date of final enrolment

31/12/2008

Locations**Countries of recruitment**

Netherlands

Study participating centre

Academic Medical Center (AMC)

Amsterdam

Netherlands

1100 DD

Sponsor information**Organisation**

Academic Medical Centre (AMC) (The Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Results and Publications

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	01/02/2011		Yes	No