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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/02/2007	**Overall study status** Completed	
Last Edited 04/07/2011	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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).

Study design
Randomised, crossover multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/01/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Barrett's oesophagus patients with low-grade dyplasia comfirmed by two expert GastroIntestinal (GI) pathologists
2. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
96

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)

Sponsor details
Department of Gastroenterology
P.O. Box 22660
Amsterdam
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Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

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

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	01/02/2011		Yes	No