Third generation autofluorescence endoscopy compared with conventional autofluorescence endoscopy for the detection of early neoplasia in Barrett’s oesophagus.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21252

Source
NTR

Brief title
TRAFI study

Health condition

Barrett's oesophagus
early neoplasia

Barrett slokdarm
vroege neoplasie

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

1. Overall histological yield of AFI II and AFI III;

2. Targeted histological yield of AFI II and AFI III;

3. Number of patients diagnosed with HGIN/EC by AFI II and AFI III.

Secondary outcome

1. Number of abnormalities detected by AFI II and AFI III;

2. The value of re-inspection of AFI-positive areas with WLE;

3. The value of re-inspection of AFI-positive areas with NBI.

Study description

Background summary

In Barrett’s oesophagus (BO), autofluorescence imaging (AFI) suffers from high false-positive (FP) rates and improved targeted detection of high-grade intraepithelial neoplasia (HGIN) and early cancer (EC) by AFI can be compensated by obtaining random biopsies. Third generation AFI may improve detection of early neoplasia and reduce FP-rate. We hypothesize that the new AFI-III system – compared to the conventional AFI-II – enhances the distinction between early neoplasia and inflammation in BO and thus reduces the amount of false positive lesions, allowing for targeted sampling and better detection of early neoplasia in BO.

This is the first randomized crossover study comparing the third generation AFI system with the conventional AFI in a selected group of patients with BE with and without dysplasia. Patients with Barrett's oesophagus with and without early neoplasia will undergo regular diagnostic imaging endoscopy for the detection of early neoplastic lesions. Patients are subsequently randomized to undergo either first AFI II or AFI III endoscopy, followed by a second endoscopy with the other system, in the same session by a second endoscopist, blinded for the results of the first endoscopy.

Study objective

We hypothesize that the new AFI-III system – compared to the conventional AFI-II – enhances

the distinction between early neoplasia and inflammation in BO and thus reduces the amount of false positive lesions, allowing for targeted sampling and better detection of early neoplasia in BO.

This is the first randomized crossover study comparing the third generation AFI system with the conventional AFI in a selected group of patients with BE with and without dysplasia.

Study design

N/A

Intervention

Patients will undergo regular diagnostic imaging endoscopy for the detection of early neoplastic lesions. Patients are subsequently randomized to undergo either first AFI II or AFI III endoscopy, followed by a second endoscopy with the other system, in the same session by a blinded endoscopist for the results of the first endoscopy

Contacts

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Eligibility criteria

Inclusion criteria

1. Age over 18 years;

2. Prior diagnosis of BO defined as columnar lined esophageal epithelium upon endoscopy and intestinal metaplasia upon histological assessment of esophageal biopsies;

3. Confirmed diagnosis of EC, HGIN, LGIN or non-dysplastic BO;

4. Written informed consent.

Exclusion criteria

1. Active erosive esophagitis grade B or higher according to the Los Angeles classification of erosive oesophagitis [17]17;

2. Advanced neoplastic lesion (i.e. any lesion considered not amendable for endoscopic treatment based its endoscopic appearance);

3. Unable to undergo biopsy sampling (e.g. due to coagulation disorders, esophageal varices).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	84
Type:	Anticipated

Ethics review

Positive opinion

Date:	18-01-2012

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34541
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3094
NTR-old	NTR3248
CCMO	NL32287.018.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34541

Study results

Summary results
Curvers WL, Herrero LA, Wallace MB, e.a. Endoscopic tri-modal imaging is more effective than standard endoscopy in identifying early-stage neoplasia in Barrett's esophagus. Gastroenterology. 2010;139(4):1106-1114.