WavSTAT study.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23646

Source NTR

Brief title WaySTAT

Health condition

- Barrett oesophagus dysplasia neoplasia advanced imaging endoscopy
- Barrett slokdarm dysplasie slokdarmkanker geavanceerde detectie endoscopie

Sponsors and support

Primary sponsor: AMC Amsterdam Source(s) of monetary or material Support: SpectraScience, San Diego, CA, USA

Intervention

Outcome measures

Primary outcome

Phase 1 will be used to develop a tissue recognition algorithm by correlating the measured fluorescence spectra to the histology of the corresponding tissue.

In phase 2 the WavSTAT optical biopsy will be validated and assessed for the following outcome parameters:

1. Sensitivity and specificity of WavSTAT for the detection of early Barrett neoplasia (HGIN/EC);

2. Additional value of WavSTAT to standard inspection with WLE, compared to inspection with WLE alone for the detection of early Barrett neoplasia (HGIN/EC).

Secondary outcome

N/A

Study description

Background summary

Aims:

1. To investigate the WavSTAT optical biopsy system by collecting fluorescence spectra of non-dysplastic and dysplastic Barrett mucosa and correlate these to the histology. The integrated optical/physical biopsy forceps will ensure spot-on correlation. The results of this study will be used to develop a differentiating, tissue recognition algorithm;

2. In a second validation study, the algorithm is integrated in the system and patients with a Barrett oesophagus will be investigated by standard white light endoscopy and with the WavSTAT optical biopsy system to assess the additional value of this differentiation tool for the detection of early neoplasia in BO.

Study objective

We hypothesize that the WavSTAT optical biopsy system may improve the endoscopists ability to detect and distinguish suspicious lesions in the Barrett oesophagus, while reducing the need for extensive biopsy protocols during surveillance endoscopies.

Study design

Phase 1 start: May 1st 2011;

Phase 1 stop: Sept 1st 2011.

Phase 2 start: Jan 1st 2012;

Phase 2 stop: Sept 1st 2012.

Intervention

Phase 1: Development of algorithm for the WavSTAT system in 20 patients;

Phase 2: Validation of the WavSTAT system in 150 patients.

Contacts

Public

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Eligibility criteria

Inclusion criteria

- 1. Age > 18 80 years;
- 2. BO with a minimal circumferential length of 2 cm;

3. BO without dysplasia (NDBO) and patients with BO referred for endoscopic work-up of HGIN or EC;

4. Signed informed consent.

Exclusion criteria

- 1. Prior history of surgical or endoscopic treatment for oesophageal neoplasia;
- 2. Presence of erosive oesophagitis (Los Angeles classification \geq B);
- 3. Inability to obtain biopsies (e.g. due to anticoagulation, coagulation disorders, varices);
- 4. Unable to provide signed informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Control: N/A , unknown	
Recruitment	
NL	

Recruitment status:	Pending
Start date (anticipated):	01-05-2011
Enrollment:	170
Туре:	Anticipated

Ethics review

Not applicable Application type:

Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2721
NTR-old	NTR2859
ССМО	NL36255.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results N/A