WavSTAT study.

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23646

Bron
NTR

Verkorte titel
WavSTAT

Aandoening

Barrett oesophagus
dysplasia
neoplasia
advanced imaging
endoscopy

Barrett slokdarm
dysplasie
slokdarmkanker
geavanceerde detectie
endoscopie

Ondersteuning

Primaire sponsor: AMC Amsterdam
Overige ondersteuning: SpectraScience, San Diego, CA, USA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Phase 1 start: May 1st 2011;

Phase 1 stop: Sept 1st 2011.

Phase 2 start: Jan 1st 2012;

Phase 2 stop: Sept 1st 2012.

Onderzoeksproduct en/of interventie

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

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior history of surgical or endoscopic treatment for oesophageal neoplasia;

2. Presence of erosive oesophagitis (Los Angeles classification ≥B);

3. Inability to obtain biopsies (e.g. due to anticoagulation, coagulation disorders, varices);

4. Unable to provide signed informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2011
Aantal proefpersonen:	170
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A