Advanced imaging using Volumetric Laser Endomicroscopy (VLE) for improved detection of early Barrett's neoplasia.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27780

Source
NTR

Health condition

- Barrett's esophagus

Dutch: Barrett slokdarm

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam
Source(s) of monetary or material Support: - Stichting Life Sciences Health ¨C TKI
- NinePoint Medical, Inc.
- Academic Medical Center Amsterdam
- Technical University Eindhoven

Intervention

Outcome measures

Primary outcome

Per area and per patient analysis of diagnostic accuracy of both VLE experts and the VLE computer algorithm.

Secondary outcome

- Inter-observer agreement of the VLE experts (Cohen's kappa coefficient)

- Identification of additional in-vivo clinical features, predictive of early neoplasia

- Time (s) to analyse a complete VLE scan;

- Experts vs. computer algorithm
- Level of confidence
- VLE experience correlated to diagnostic accuracy
- Diagnostic accuracy of BE neoplasia using single frames versus multi-frame regions of interest versus full scan analysis

Study description

Background summary

The aim of this current study is to evaluate and validate diagnostic accuracy of VLE experts and a VLE computer algorithm for the detection of BE neoplasia.

Study objective

1) VLE experts can distinguish BE neoplasia from non-dysplastic tissue on VLE

2) A computer algorithm is able to detect BE neoplasia on VLE

Study design

Start inclusion: October 9, 2017.

Intervention

Intervention: Volumetric Laser Endomicroscopy laser marking (NvisionVLE Marking Probe).

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Males or females aged ≥ 18 years

- Known BE, defined as columnar lined epithelium of the esophagus containing intestinal metaplasia upon biopsy.

- Ability to provide written, informed consent to participate in the trial

Exclusion criteria

- Patients for who use of the NvisionVLE Imaging System would be in conflict with the Instructions For Use (IFU).

- Presence of an esophageal mass that precludes full distension of the balloon from the NVisionVLE Marking Probe

- Patients with esophageal strictures that would prevent adequate expansion of the balloon from the NvisionVLE Marking Probe.

- Patients with known inflammatory disease, esophageal tears or ulcers, which would prohibit full distention of the balloon from the NvisionVLE Marking Probe.

- Contraindications for ER and/or obtain biopsies (e.g. due to anticoagulation, coagulation disorders, esophageal varices)

- Previously treated dysplasia by either ER and/or ablation therapy..

- Unable to provide signed informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2017
Enrollment:	50
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	02-10-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47641
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6540
NTR-old	NTR6728
CCMO	NL61613.018.17
OMON	NL-OMON47641

Study results

Summary results
Pre-work:
Swager A. et al. Feasibility of laser marking in Barrett's esophagus with volumetric laser endomicroscopy: first-in-man pilot study. Gastrointest Endosc. 2017 Sep;86(3):464-472. doi: 10.1016/j.gie.2017.01.030.