Feasibility of real-time computer guided Volumetric Laser Endomicroscopy (VLE) targeted biopsies for improved detection of early Barrett's Neoplasia

No registrations found.

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

Summary

ID

NL-OMON27008

Source
Nationaal Trial Register

Brief title
VLE CAD pilot study

Health condition

Barrett esophagus with and without neoplasia

Sponsors and support

Primary sponsor: Top Sector Life Sciences & Health: Health Holland & TKI, NinePoint Medical
Source(s) of monetary or material Support: Top Sector Life Sciences & Health: Health Holland & TKI, NinePoint Medical

Intervention

Outcome measures

Primary outcome

Feasibility of a real-time VLE computer algorithm for the detection of BE neoplasia

Secondary outcome

a) Diagnostic performance of CAD targeted biopsies (accuracy, sensitivity, specificity)

b) Proportion of VLE-CAD guided biopsies positive for dysplasia, assessed at a per biopsy & per patient level

c) Safety

d) VLE procedure time

e) Total number of VLE-CAD guided biopsies per patient

Study description

Background summary

Feasibility of a volumetric laser endomicroscopy (VLE) computer algorithm is evaluated for obtaining real-time targeted biopsies for improved detection of early Barrett's neoplasia

Study objective

VLE computer algorithm is feasible for obtaining real-time targeted biopsies for improved detection of BE neoplasia

Study design

1 endoscopy where the algorithm is evaluated. Histopathology is checked subsequently to assess the diagnostic yield

Intervention

Endoscopy as planned for routine clinical care, where VLE algorithm targeted biopsies are evaluated for the detection of BE neoplasia

Contacts

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Eligibility criteria

Inclusion criteria

• Age > 18 years;
• Ability to provide written, informed consent (approved by IRB) and understand the responsibilities of trial participation.
• Minimum Barrett's extent (from Prague criteria) M ≥ 2cm;
• Known BE, defined as columnar lined epithelium of the esophagus containing intestinal metaplasia upon biopsy, with or without dysplasia (low-grade or high-grade dysplasia or early adenocarcinoma);

Exclusion criteria

• Presence of an esophageal mass that precludes full distention of the balloon from the NvisionVLE Optical Probe;
• Patients with known esophageal strictures, esophageal tears or ulcers, which would prohibit full distention of the balloon from the NvisionVLE Optical Probe;
• Contraindications for endomucosal resection (EMR) and/or obtaining biopsies (e.g. due to anticoagulation, coagulation disorders, esophageal varices);
• Patients within four weeks of receiving targeted forceps biopsies and/or EMR;
• 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:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2020
Enrollment:	18
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	28-10-2019
Application type:	First submission

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	NL8133
Other	METC AMC : METC 2019_195

Study results