A Multicenter Clinical Validation Study of EsoGuard® on Samples Collected Using EsoCheck® for the Detection of Barrett*s Esophagus with and without Dysplasia, and/or Esophageal Adenocarcinoma, using Esophagogastroduodenoscopy as the Diagnostic Comparator

Published: 20-08-2020
Last updated: 04-07-2024

The overall objective for this study is to train and validate EsoGuard-based diagnosis characteristics

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON52452

Source
ToetsingOnline

Brief title
EG-CL-102

Condition

- Gastrointestinal conditions NEC

Synonym
Barrett's Esophagus

Research involving
Human

Sponsors and support

Primary sponsor: Lucid Diagnostics Inc.
Source(s) of monetary or material Support: bedrijf voor medische hulpmiddelen

Intervention

Keyword: Barrett's Esophagus, esophageal adenocarcinoma, Esophagogastroduodenoscopy

Outcome measures

Primary outcome

Primary Objective: Assess the sensitivities of EsoGuard-based diagnosis

broadly, in patients with any degree of disease along the full Barrett*s

Esophagus (BE) to intramucosal carcinoma (IMC)/esophageal adenocarcinoma (EAC)

spectrum.

Secondary outcome

Key Secondary Objective:

* Assess the specificity of EsoGuard-based diagnosis in patients without

disease (Controls);

Secondary Objective:

* Assess the Negative (LR-) and Positive likelihood ratios (LR+) of

EsoGuard-based diagnosis broadly, in patients with disease (Cases) or without

disease (Controls).

Study description

Background summary

The current gold standard procedure for diagnosing BE and EAC is to obtain tissue samples during an esophagogastroduodenoscopy (EGD) and then have the tissue samples looked at under a microscope. This procedure is burdensome invasive and expensive.
The new procedure being tested uses the EsoCheck device to obtain cells from the esophagus. The cells are then assessed with the EsoGuard laboratory test. Compared with endoscopy, the EsoGuard laboratory test, on samples collected using EsoCheck, may offer an accurate, lower cost, non-invasive approach to screen subjects for BE and EAC.

Study objective

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Study design

Multicenter Case-Control Study

Intervention

EsoCheck procedure and EGD procedure

Study burden and risks

Participants will experience as an additional burden:
- Esocheck procedure
- follow-up telephone call

The following adverse effects are common (occurs in 1 in 10 people or more):
• Discomfort (e.g., throat soreness or irritation, procedure anxiety)
• Gagging while swallowing the balloon capsule catheter

Mild gagging and discomfort (including sore throat) experienced during, and within the first day after EsoCheck cell collection is are an expected normal physiological response upon swallowing the device and is are not considered an adverse device event.
Moderate to severe discomfort upon swallowing the device should be considered an adverse device event and appropriate documentation completed.

These adverse effects occur, but not often:
• Transient chest pressure, pain upon inflation of the balloon or device movement into or in the esophagus

• Intestinal obstruction if the balloon/capsule is separated from the catheter
• Bleeding in or accidental tearing or poking a hole in the esophagus
• Tussue trauma (e.g., scratching, scraping, irriation or creating a sore in the esophagus)
• Infection
• Spilling over of stomach contents into the lungs
• Allergic reaction to silicone

Contacts

Public
Lucid Diagnostics Inc.

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US
Scientific
Lucid Diagnostics Inc.

360 Madison Avenue Floor 25
New York NY 10017
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

EsoCheck* Device Administration Training Phase:
1) Males and Females age 22 and over
2) No solid foods eaten for at least 2 hours prior to EsoCheck* procedure

Main Study Phase
All Patients:
-1) Men aged 50 years and above
2) >=5 years either of
o Gastroesophageal reflux disease (GERD) symptoms,
o GERD treated with proton pump inhibitor (PPI) therapy (whether symptom control is achieved or not), or
o any combination of treated and untreated periods, as long the cumulative total is at least 5 years
o First-degree relative with BE or EAC
3) No solid foods eaten for at least 2 hours prior to EsoCheck procedure
4) One or more of the following:
o Caucasian race
o Current or past history of cigarette smoking
o Body mass index (BMI) of at least 30 kg/m2
o First-degree relative with BE or EAC

Additional Inclusion Criteria for Cases:
Previous diagnosis of indefinite for dysplasia (IFD), NDBE, LGD,HGD and/or IMC
1, Previous diagnose by EGD of:
a. NDBE at any time, or,
b.LGD, HGD, or IMC within 4 months prior to study enrollment unless it is certain, at the time of enrollment, that a full set of biopsies per Seattle Protocol will be taken during the Study EGD, including biopsy of the most visually advanced lesion(s). In such a case, the EGD establishing entry diagnosis of LGD, HGD or IMC diagnosis can have been made at any time prior to enrollment.
2) Indicated for surveillance EGD or for therapeutic EGD
3) Able to provide the original glass slide(s) of biopsy specimens from most recent prior EGD

Exclusion criteria

EsoCheck* Device Administration Training Phase:
1) Inability to provide written informed consent
2) On anti-coagulant drug(s) that cannot be temporarily discontinued, (as defined in study memo CO/EG-CL-102/2020/002 and provided as an appendix to this protocol)
3) Known history of esophageal varices or esophageal stricture
4) Any contraindication, as deemed in Investigator*s medical judgment, to undergoing the EsoCheck* procedure, undergoing the EGD procedure, and/or having biopsies taken, including but not limited to due to comorbidities such as coagulopathy or a known history of esophageal diverticula, esophageal fistula, and/or esophageal ulceration

5) Known difficulty swallowing (dysphagia) or painful swallowing (odynophagia), including swallowing pills, which in the opinion of the Investigator will preclude succesfull swollowing of the EsoCheck capsule.
6) Anxiety, which in the opinion of the investigator will preclude successful swallowing of the EsoCheck capsule
7) Oropharyngeal Tumor
8) History of esophageal or gastric surgery, with exception of uncomplicated surgical fundoplication procedure
9) History of myocardial infarction or cerebrovascular accident within past 6 months
10) Any known lesion which, in the opinion of the endoscopist, obstructs greater than 25% of the esophageal lumen
11) Prior participation in PR-0139/EG-CL-101 (Lucid BE Screening Study), PR-1038/EG-CL-102 and/or the BETRNet study (NCT00288119).
12) Prior EGD during which a therapeutic procedure such as, but not limited to, ablation, cryotherapy or endoscopic mucosal resection, was performed for the treatment of BE and/or EAC.
13) History of esophageal motility disorder
14) Currently implanted Linx device

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Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2021
Enrollment:	175
Type:	Actual

Medical products/devices used

Generic name:	EsoGuard en EsoCheck
Registration:	No

Ethics review

Approved WMO Date:	20-08-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2021

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	03-02-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	19-06-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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
ClinicalTrials.gov	NCT04295811
CCMO	NL73093.018.20