Disposable, transnasal versus conventional upper gastrointestinal endoscopy: a diagnostic accuracy study in patients referred for diagnostic evaluation of the esophagus

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Determine the diagnostic accuracy of the E.G.Scan 2.0* compared to conventional upper endoscopy in patients referred for diagnostic upper endoscopy to evaluate esophageal disorders.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON40705

Source
ToetsingOnline

Brief title
SCAN study

Condition

- Gastrointestinal conditions NEC

Synonym
esophageal lesions

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: disposable, esophagus, transnasal, upper endoscopy

Outcome measures

Primary outcome

Diagnostic accuracy of the E.G.Scan 2.0 * compared to conventional upper

endoscopy in patients referred for diagnostic upper endoscopy as determined by

sensitivity and specificity for upper GI lesions

Secondary outcome

- technical success

- safety

- quality of procedure (evaluated by the endoscopist)

of the E.G.Scan 2.0 * compared to conventional upper endoscopy in patients

referred for diagnostic upper endoscopy evaluate esophageal disorders

Study description

Background summary

Upper gastrointestinal (GI) endoscopy is the procedure of choice for the diagnosis and treatment of esophageal disorders. Since costs but also complications of upper endoscopy are related to sedation, efforts have been made to improve the tolerance for upper endoscopy and to reduce the need for sedation. Small-caliber endoscopes have been developed which can be introduced through the mouth or nose without the need for sedation. Several large studies have been conducted with regard to tolerance, safety, feasibility and accuracy

of unsedated small-caliber transnasal upper endoscopy. Recently a new endoscopy system, the E.G.Scan 2.0*, has been developed which is compact and is partly disposable. For this design endoscope, there is no need for the laborious and costly process of cleansing and desinfection, which needs to be done with a standard endoscope. Besides, the E.G.Scan 2.0* can be used outside the endoscopy unit, which allows upper endoscopy outside the hospital.

Study objective

Determine the diagnostic accuracy of the E.G.Scan 2.0* compared to conventional upper endoscopy in patients referred for diagnostic upper endoscopy to evaluate esophageal disorders.

Study design

The study consists of a small feasibility study and a fully paired diagnostic accuracy study.

Intervention

Transnasal upper endoscopy performed with the E.G.Scan 2.0 * (IntroMedic Co., Ltd., Seoul, Korea) followed by
conventional upper endoscopy.

Study burden and risks

The potential benefit for patients is a better overall tolerance of the procedure and performance of upper endoscopy outside the hospital. In addition, direct and indirect costs associated with upper endoscopy can be saved as it can be imagined that in the future, patients can undergo upper endoscopy in an outpatient setting or even by a specialized general practitioner. The burden consists of undergoing an additional upper endoscopy of the esophagus, which takes approximately 10 minutes. Patients will be asked to contact the coordinating investigator in case of (serious) adverse events with 14 days after the procedure. No additional study visits are necessary. The risk associated with participation is pain in the nasopharyngeal area, (self-limiting) epistaxis (0% * 22.6%) or vasovagal collapse (0%- 0.3%).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Indication for diagnostic upper endoscopy to evaluate esophageal disorders
- Age older than 18 years
- Written informed consent

Exclusion criteria

- Therapeutic endoscopic intervention
- Known bleeding diathesis
- Concurrent anticoagluation therapy
- History of trauma/surgery of nose or nasal cavity
- Recurrent epistaxis (> 1 episode / 3 months)
- Altered anatomy of the upper gastroesophageal tract due to suergy of the esophagus
- Implantable pacing device

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	147
Type:	Anticipated

Medical products/devices used

Generic name:	E;G.Scan II; disposable scope
Registration:	No

Ethics review

Approved WMO

Date:	06-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL47629.041.13