COMPARING CHROMOENDOSCOPY AND WHITE LIGHT VIDEO ENDOSCOPY FOR ESOPHAGEAL DYSPLASIA AND CANCER SURVEILLANCE IN PATIENTS WITH ACHALASIA

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The aim of this study is to compare the sensitivity of chromoendoscopy with Lugol*s solution with conventional white light video endoscopy in diagnosing esophageal dysplasia and cancer in patients with achalasia.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON30825

Source
ToetsingOnline

Brief title
none

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Esophageal motility disorder, movement disorder of the esophagus

Research involving
Human

Sponsors and support

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

Intervention

Keyword: achalasia, chromoendoscopy, neoplasia, surveillance

Outcome measures

Primary outcome

Primary end point is the difference between WLE and CE for detection of

dysplastic

lesions or oesophageal carcinoma during gastroscopy in patients with achalasia.

Secondary outcome

- Histological difference of the lesions detected only by WLE or only by CE

- Duration of the procedure for WLE and CE

Study description

Background summary

COMPARING CHROMOENDOSCOPY AND WHITE LIGHT VIDEO ENDOSCOPY FOR ESOPHAGEAL DYSPLASIA AND CANCER SURVEILLANCE IN PATIENTS WITH ACHALASIA

Achalasia is a rare condition, characterized by a functional obstruction of the esophagus caused by failed relaxation of the lower oesophageal sphincter (LES) in combination with absent peristalsis of the distal esophagus. After therapy food-stasis often persists and can lead to chronic inflammation, hyperplasia of the epithelium, dysplasia and squamous cell carcinoma (SCC). Achalasia patients are known to have a considerably increased risk for esophageal cancer, this risk has been reported to be up to 140 times higher than in the normal population. For screening or surveillance endoscopy flexible white light endoscopes are routinely used. Studies evaluating the value of chromoendoscopy in the detection of early gastro intestinal neoplasia showed promising results. No studies have been performed to evaluate the clinical significance of implementing chromoendoscopy as standard surveillance modality for dysplasia

and cancer in patients with achalasia.

Study objective

The aim of this study is to compare the sensitivity of chromoendoscopy with Lugol*s solution with conventional white light video endoscopy in diagnosing esophageal dysplasia and cancer in patients with achalasia.

Study design

Observational study with invasive measurements.

Study burden and risks

The burden associated with participation is that the patients have to undergo two endoscopies instead of one. A gastroscopy is a save investigation. Still complications can occure (1 or 2 times each 1000 gastroscopies). An airway infection or pneumonia can be caused by aspiration of esophageal- and/ or stomach-contents. This occures more often in patients who received conscious sedation. Occasionally a little perforation in the esophagus, or very rarely, in the stomach, can occur. After biopsy there might occur a bleeding. The more interventions take place, the greater the risk of complications. A side effect of chromoendoscopy can be an allergic reaction due to the Lugol's solution applied to the esophagus as this solution contains iodine. For this reason people with a known iodine allergy cannot be included in this study. Hyperthyroidism is an exclusion criterion as well.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
3015 CE Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

A) Age 18 years or older
B) Patients with primary achalasia as diagnosed according to standard criteria

Exclusion criteria

A) Under 18 years of age
B) Known allergy against iodine
C) Hyperthyroidism
D) Esophageal varices
E) Barrett*s esophagus
F) Heart failure (New York Heart association III-IV)
G) Coagulopathy (prothrombin time < 50% of control; partial thromboplastin time > 50 seconds) or anticoagulant use that can not be discontinued

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:	Recruiting
Start date (anticipated):	07-01-2008
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	21-03-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL16381.078.07