

# FEASIBILITY OF ENDOSCOPY GUIDED FIDUCIAL MARKER PLACEMENT IN PATIENTS WITH ESOPHAGEAL TUMORS

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To study the feasibility of the endoscopic guided placement of gold markers in patients with esophageal tumors and to determine the utility of the markers tumor delineation and for positional verification during treatment.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal neoplasms malignant and unspecified
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON38822

### Source

ToetsingOnline

### Brief title

esophageal fiducial study

### Condition

- Gastrointestinal neoplasms malignant and unspecified

### Synonym

esophageal cancer

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** esophageal cancer, fiducials, radiotherapy, tumordelineation

## Outcome measures

### Primary outcome

- feasibility and toxicity of endoscopic placement of goldmarkers in the oesophageal wall
- utility of the markers for delineation of the tumortargetvolume
- utility of the markers for positional verification and correction during external radiation (image guided radiotherapy)

### Secondary outcome

- analysis of tumor deformation during radiotherapy
- analyses of effect of breathing on tumormobility during radiotherapy

## Study description

### Background summary

Interstitial placement of goldmarkers is a standard procedure to increase radiation accuracy in the treatment of bladder carcinoma, prostate carcinoma and pancreas carcinoma at the dept. of Radiotherapy in the AMC.

#### 1.10. STUDY POPULATION

Patients diagnosed with esophageal cancer referred for radiotherapy in the AMC

Inclusion criteria:

Histologically proven esophageal cancer

Referred for radio(chemo)therapy

Exclusion criteria:

Contraindication for an endoscopy of the esophagus

Coagulopathy or platelets < 40.000

### Study objective

To study the feasibility of the endoscopic guided placement of gold markers in patients with esophageal tumors and to determine the utility of the markers tumor delineation and for positional verification during treatment.

## **Study design**

a prospective feasibility study to test the feasibility and utility of endoscopic placement of gold markers in the esophagus.

## **Intervention**

endoscopy of the esophagus with implantation of 3 gold markers in the esophageal wall at the level of the tumor

## **Study burden and risks**

The burden and risks for the patients are estimated as low:

- An endoscopy is a standard procedure without risks and has already been part of the diagnostic trajectory for the patient
- Implantation of markers could cause an infection, but the risk is estimated low, considering the very low risk of infection during gold markers implantation in prostate, bladder and pancreas cancer (<1%). Short course prophylactic antibiotics will reduce this risk.
- the risk of a bleeding is estimated as low, and if occurring, will be small considering the small diameter of the markers and is assumed to be self-limiting. This statement is made based on the broad experience with esophageal biopsies.
- gold is non-allergic
- gold markers that become unstuck will be released from the body with the defecation without complaints

## **Contacts**

### **Public**

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### **Scientific**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

esophageal cancer

referred for curative radiotherapy

### Exclusion criteria

signs of perforation

signs of esophageal infections

coagulopathy

## Study design

### Design

**Study type:** Interventional

Masking:

Open (masking not used)

Control:

Uncontrolled

Primary purpose:

Diagnostic

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 06-03-2013  
Enrollment: 30  
Type: Actual

## Medical products/devices used

Generic name: endoscopic implantation of markers in the esophageal wall  
Registration: Yes - CE intended use

## Ethics review

Approved WMO  
Date: 04-03-2013  
Application type: First submission  
Review commission: METC Amsterdam UMC  
Approved WMO  
Date: 08-10-2013  
Application type: Amendment  
Review commission: METC Amsterdam UMC  
Approved WMO  
Date: 07-03-2014  
Application type: Amendment  
Review commission: METC Amsterdam UMC

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24170  
Source: NTR  
Title:

**In other registers**

Register	ID
CCMO	NL43179.018.13
OMON	NL-OMON24170