

# A randomized comparison of a fully covered self expandable metal stent versus a partially covered self expandable metal stent in malignant esophageal strictures

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To compare a fully covered metal stent versus a partially covered metal stent in patients with dysphagia due to an incurable malignant stenosis of the esophagus or cardia.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal stenosis and obstruction
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON35282

### Source

ToetsingOnline

### Brief title

COPAC

### Condition

- Gastrointestinal stenosis and obstruction
- Gastrointestinal neoplasms malignant and unspecified

### Synonym

Malignant esophageal stricture

### 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:** fully covered metal stent, malignant esophageal stricture, partially covered metal stent, randomized controlled trial

## Outcome measures

### Primary outcome

Recurrent dysphagia. This is defined as occurrence of dysphagia due to a stent or tumour related cause such as tumor in- or overgrowth, stent migration or food impaction.

### Secondary outcome

Technical success of metal stent placement, clinical success defined as improvement of dysphagia score, complication rate, quality of life and survival

## Study description

### Background summary

Adequate treatment of dysphagia is essential in palliative care of patients with incurable esophageal cancer. Metal stent placement is a minimally invasive procedure and is rapidly effective in relieving dysphagia. However, recurrent dysphagia occurs in around 40% of patients. It has been demonstrated that metal stents, which are covered with a membrane are effective in reducing the number of reinterventions compared with metal stents without covering. Randomized studies comparing fully covered metal stents with partially covered metal stents are scarce.

### Study objective

To compare a fully covered metal stent versus a partially covered metal stent in patients with dysphagia due to an incurable malignant stenosis of the

esophagus or cardia.

## Study design

Prospective, randomized controlled study with a follow-up of 6 months

## Intervention

In one treatment group a fully covered metal stent will be placed. In the other treatment group a partially covered metal stent will be inserted.

## Study burden and risks

Patients will be contacted by telephone at regular intervals for assessing questionnaires. In our opinion this will not put burden on patients significantly. The randomisation between both types of stents will not expose patients to additional risks. It is unclear which type of stent is preferable with respect to risks and complications.

## 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

Malignant stricture of the esophagus or cardia

No curative treatment options available

Dysphagia grade of at least 2 (able to swallow semi-solid soft foods)

Informed consent

Age ≥ 18 years

### Exclusion criteria

Previous treatment with self-expandable metal stent for same condition

Evidence of tumor within 2 cm of the upper esophageal sphincter.

Presence of an esophago-tracheal or -bronchial fistula or both.

Not able to undergo upper endoscopy

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2012

Enrollment:	72
Type:	Actual

## Ethics review

Approved WMO	
Date:	20-03-2012
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	NL38111.078.11