

# Placement of markers in the stomach to increase visibility of position and motion of the stomach on CT scans, with the aim to improve the accuracy of radiotherapy for patients with gastric cancer

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Endoscopic placement of fiducial markers in patients with gastric cancer is feasible and beneficial for patient position verification.

|                             |                          |
|-----------------------------|--------------------------|
| <b>Ethische beoordeling</b> | Positief advies          |
| <b>Status</b>               | Werving nog niet gestart |
| <b>Type aandoening</b>      | -                        |
| <b>Onderzoekstype</b>       | Interventie onderzoek    |

## Samenvatting

### ID

NL-OMON27588

### Bron

Nationaal Trial Register

### Verkorte titel

MaagART-01

### Aandoening

Gastric cancer; radiotherapy

## Ondersteuning

**Primaire sponsor:** Academic Medical Center (AMC)

**Overige ondersteuning:** Materials: KWF grant #10882 "Individualized image-guided adaptive radiotherapy for resectable gastric cancer: now and in the future."

## Onderzoeksproduct en/of interventie

## **Uitkomstmaten**

### **Primaire uitkomstmaten**

Feasibility of using fiducial markers in image-guided pre-operative radiotherapy for patients with gastric cancer.

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

For pre-operative radiotherapy, the entire stomach with surrounding lymph nodes is included in the clinical target volume. However, the stomach is a highly mobile organ, displaying deformation and motion due to breathing, gastrointestinal filling and peristalsis. Daily cone-beam CT-based patient position verification is used, but visibility of the stomach on cone-beam CT (CBCT) is limited. In our study, we will investigate the feasibility and safety of endoscopic placement of fiducial markers in the stomach. We hypothesize that fiducial markers with high visibility on CT and CBCT benefit CBCT-based position verification and thus improve the accuracy of pre-operative radiotherapy for patients with gastric cancer.

### **Doel van het onderzoek**

Endoscopic placement of fiducial markers in patients with gastric cancer is feasible and beneficial for patient position verification.

### **Onderzoeksopzet**

Final analysis will take place after inclusion has been completed.

### **Onderzoeksproduct en/of interventie**

Included patients will undergo endoscopic placement of fiducial markers in the stomach. In addition, extra imaging (CBCT and CT) will be obtained.

## **Contactpersonen**

### **Publiek**

Department of Radiotherapy

Astrid Horst, van der  
Meibergdreef 9

Amsterdam 1105 AZ  
The Netherlands

## **Wetenschappelijk**

Department of Radiotherapy

Astrid Horst, van der  
Meibergdreef 9

Amsterdam 1105 AZ  
The Netherlands

## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

- Patients with histologically proven primary gastric cancer;
- Referred for pre-operative radiotherapy in the Academic Medical Center;
- Written informed consent.

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

- Coagulopathy or platelets level < 40.000;
- Endoscopic suspicion of fistula;
- Endoscopic suspicion of active gastric infections;
- High risk for sedation;
- Unwilling to participate in the study and/or sign informed consent;
- Pregnant;

- Age < 18 years.

## Onderzoeksopzet

### Opzet

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| Onderzoeksmodel: | Anders                  |
| Toewijzing:      | N.v.t. / één studie arm |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | N.v.t. / onbekend       |

### Deelname

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-06-2018               |
| Aantal proefpersonen:   | 25                       |
| Type:                   | Verwachte startdatum     |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 29-05-2018       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50759  
Bron: ToetsingOnline  
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID             |
|----------|----------------|
| NTR-new  | NL7036         |
| NTR-old  | NTR7241        |
| CCMO     | NL65080.018.18 |
| OMON     | NL-OMON50759   |

## Resultaten