# Fluorescent angiography using indocyanine green during esophagectomy with continuity restoration to prevent anastomotic complications

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Intraoperative real-time FA using ICG can assess perfusion, and thereby enables precise delineation of the ideal site for anastomosis and assessment of final anastomotic vitality. However, no quantitative threshold of the fluorescence signal is...

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON24815

**Bron**
Nationaal Trial Register

**Verkorte titel**
FA UpperGI

**Aandoening**

Esophageal cancer

### Ondersteuning

**Primaire sponsor:** None
**Overige ondersteuning:** None

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The primary outcomes are various quantitative parameters of FA, and to relate those parameters to surgical morbidity. Quantitative parameters include time to fluorescence in target or surrounding tissue.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Anastomotic complicaties after esophagectomy with continuity restoration are associated with a high mortality. Among the risk factors that influence anastomotic integrity, poor perfusion is a surgically modifiable factor. Intraoperative real-time fluorescence angiography (FA) using indocyanine green (ICG) can assess perfusion, and thereby enables precise delineation of the ideal site for anastomosis and assessment of final anastomotic vitality. Although management according to FA findings seems to lower anastomotic complications rates afer esophagectomy, complications still occur. Besides the multifactorial etiology of anastomotic complications, an explanation might be that no fluorescent threshold is known for complications.
In this monocenter prospective explorative study (IDEAL phase 2S study), we aim to evaluate time to fluorescent enhancement as a quantitative fluorescent value, and to correlate the values with surgical morbidity, including anastomotic leakage, graft necrosis and anastomotic strictures.

### Doel van het onderzoek

Intraoperative real-time FA using ICG can assess perfusion, and thereby enables precise delineation of the ideal site for anastomosis and assessment of final anastomotic vitality. However, no quantitative threshold of the fluorescence signal is known for adequate perfusion. Time dependent change of the fluorescent signal seems a promising method for objective analysis of tissue perfusion. The hypothesis is that a quantitative threshold for this time dependent change can be identified to predict surgical morbidity.

### Onderzoeksopzet

Surgery and follow-up

### Onderzoeksproduct en/of interventie

Intraoperative FA is performed after intravenous ICG injection (0.05mg/kg/bolus). Time to first fluorescent enhancement is assessed using a digital clock and will be noted in a case-report

form.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

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

- Age of 18 years and older;
- Undergoing esophagectomy with gastric conduit reconstruction;
- Undergoing esophagectomy with continuity restoration, graft other than gastric conduit;
- Intraoperative FA to assess perfusion of graft and anastomosis;
- No objection for use of data.

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

- Allergy to ICG, iodide or sodium iodide;
- Hyperthyroidism or benign thyroid tumor;
- Thyroid examination using radioactive iodide <1 week;
- Breast-feeding;
- Objection for use of data.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-06-2018 |
| Aantal proefpersonen: | 70 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nee

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 14-04-2020 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

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

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL8527 |
| Ander register | METC AMC : W19_145 (outside the realm of the Dutch WMO law) |

# Resultaten