# Lymfeklierdetectie bij borstkankerpatiënten via fluorescentiebeeldvorming met behulp van Indocyanine Groen: De INFLUENCE Studie

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The detection rate of the ICG method to identify the SLN in breast cancer patients is not inferior to the standard 99mTc method.

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | Borst therapeutische verrichtingen |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON29593

**Bron**
Nationaal Trial Register

**Verkorte titel**
INFLUENCE

### Aandoening

- Borst therapeutische verrichtingen

**Aandoening**

Breast cancer

**Betreft onderzoek met**
Mensen

## Ondersteuning

**Primaire sponsor:** St. Antonius Hospital
**Overige ondersteuning:** St. Antonius Innovatiefonds 2019: € 45.000,- (for the lease of the fluorescent camera and medicine)

## Onderzoeksproduct en/of interventie

- Chirurgische ingreep

**Toelichting**

## Uitkomstmaten

**Primaire uitkomstmaten**

Identification rate of SLNs by the fluorescent signal of ICG and by 99mTc.

# Toelichting onderzoek

**Achtergrond van het onderzoek**

Rationale: Identifying lymphatic metastases is an important prognostic factor in the survival rate of breast cancer and the presence of lymphatic metastases carries consequences for further treatment. The golden standard for obtaining the SLN in patients with breast cancer is radio guided surgery with radioisotope technetium (99mTc). However, the use of 99mTc may present adverse effects and logistical challenges. A promising alternative method is the use of fluorescence imaging using indocyanine green (ICG). It is non-ionizing, easy to apply, patient- and surgeon friendly, safe, easy to obtain and cost-effective. Objective: In this non-inferiority study, we aim to identify the diagnostic value of indocyanine green (ICG) fluorescence imaging for SLN mapping versus the standard-of-care 99mTc in the SLN procedure for breast cancer patients. Study design: This is a single institution, single arm diagnostic efficacy trial identifying the diagnostic value of indocyanine green (ICG) fluorescence imaging for SLN mapping versus the standard-of-care radioisotope technetium (99mTc) in the SLN procedure for breast cancer. Study population: Women with breast cancer who are admitted to the St. Antonius Hospital. Inclusion criteria include clinically node-negative, invasive early T1 or T2 breast cancer conformed by biopsy, preoperative axillary ultrasound to confirm clinical node-negative status and indication for lumpectomy with SLN procedure. Intervention: All included patients will receive standard of care implying 99mTc injection the day before surgery. Consequently, 5 mg (2 ml) ICG will be injected periareolar after administration of general anaesthesia and before incision. The lymphatic vessels and sentinel lymph node will be visualized by fluorescent imaging usng the Fluobeam800 © camera. A surgically considered incision in the axilla is made while taking into account the marker of the ICG hotspots. Then the excised nodes are tested for 99mTc activity with the

standard gamma detecting probe as control. Lastly, the axilla will be explored with the standard gamma-probe for residual lymph nodes, and by common sight and palpation as a control. Main study parameters/endpoints: Identification rate of SLNs by the fluorescent signal of ICG compared to the standard of care 99mTc.

### Doel van het onderzoek

The detection rate of the ICG method to identify the SLN in breast cancer patients is not inferior to the standard 99mTc method.

### Onderzoeksopzet

Intraoperative, postoperative (pathology outcomes) and short term complications, and for complications such as lymph edema 6 months postoperatively.

### Onderzoeksproduct en/of interventie

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## Contactpersonen

### Publiek

St. Antonius Nieuwegein
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### Wetenschappelijk

St. Antonius Nieuwegein
Claudia Bargon

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# Deelname eisen

**Leeftijd**
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

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

- Clinically node-negative, invasive early T1 or T2 breast cancer confirmed by biopsy. - Preoperative axillary ultrasound to confirm clinical node-negative status. - Indication for lumpectomy and SLN procedure. - Written informed consent according to ICH/GCP and national regulations.

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

- Patients < 18 years old. - Mastectomy. - Known allergy for indocyanine green (ICG) or radioisotope technetium (99mTc) or intravenous contrast, iodine, shellfish. - Other concurrent or history of other solid tumor. - Hyperthyroidism or thyroid cancer. - T3 breast cancer confirmed by biopsy. - Palliative surgery for locally advanced breast cancer (cT4). - Pregnancy or breast feeding. - Psychological, familial, sociological or geographical factors that could potentially hamper compliance with the study protocol.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Fase onderzoek: | 4 |
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Enkelvoudig |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Enkelblind |
| Controle: | Actieve controle groep |
| Doel: | Diagnostiek |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 28-08-2020 |
| Aantal proefpersonen: | 100 |
| Type: | Werkelijke startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

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

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 17-02-2020 |
| Soort: | Eerste indiening |
| Toetsingscommissie: | Medical Research Ethics Committees United (MEC-U)<br><br>Postbus 2500<br>3430 EM Nieuwegein<br>088 320 8784<br>info@mec-u.nl |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49864
Bron: ToetsingOnline
Titel:

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

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL8402 |
| CCMO | NL71617.100.19 |
| OMON | NL-OMON49864 |

# Resultaten

Datum resultaten gemeld: 31-07-2023

Totaal aantal deelnemers: 102

**Samenvatting resultaten**
"Objective: The aim was to compare the (sentinel) lymph node detection rate of indocyanine green (ICG)-fluorescent imaging versus standard-of-care 99m Tc-nanocoilloid for sentinel lymph node (SLN)-mapping.

Background: The current gold standard for axillary staging in patients with breast cancer is sentinel lymph node biopsy (SLNB) using radio-guided surgery using radioisotope technetium ( 99m Tc), sometimes combined with blue dye. A promising alternative is fluorescent imaging using ICG.

Methods: In this noninferiority trial, we enrolled 102 consecutive patients with invasive early-stage, clinically node-negative breast cancer. Patients were planned for breast conserving surgery and SLNB between August 2020 and June 2021. The day or morning before surgery, patients were injected with 99m Tc-nanocolloid. In each patient, SLNB was first performed using ICG-fluorescent imaging, after which excised lymph nodes were tested with the gamma-probe for 99m Tc-uptake ex vivo, and the axilla was checked for residual 99m Tc-activity. The detection rate was defined as the proportion of patients in whom at least 1 (S)LN was detected with either tracer.

Results: In total, 103 SLNBs were analyzed. The detection rate of ICG-fluorescence was 96.1% [95% confidence interval (95% CI)=90.4%-98.9%] versus 86.4% (95% CI=78.3%-92.4%) for 99m Tc-nanocoilloid. The detection rate for pathological lymph nodes was 86.7% (95% CI=59.5%-98.3%) for both ICG and 99m Tc-nanocoilloid. A median of 2 lymph nodes were removed. ICG-fluorescent imaging did not increase detection time. No adverse events were observed.

Conclusions: ICG-fluorescence showed a higher (S)LN detection rate than 99m Tc-nanocoilloid, and equal detection rate for pathological (S)LNs. ICG-fluorescence may be used as a safe and effective alternative to 99m Tc-nanocoilloid for SLNB in patients with early-stage breast cancer."

**Ongewenste voorvallen**
No ICG-related adverse events.