# Indocyanine green dye in surgical treatment of laryngeal cancer

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

# **Summary**

# ID

NL-OMON27297

**Source** Nationaal Trial Register

**Brief title** N/A

#### **Health condition**

laryngeal cancer

# **Sponsors and support**

**Primary sponsor:** University Medical Center Groningen **Source(s) of monetary or material Support:** N/A

## Intervention

## **Outcome measures**

#### **Primary outcome**

We want to estimate cut off values for clinically appropriate hypoperfusion of the pharyngeal mucosa and the skin in the neck.

#### Secondary outcome

We want to compare perfusion rate of PTL to perfusion rate in STL in order to create cut off values for both patient categories.

# **Study description**

#### **Background summary**

In advanced laryngeal cancer (LC) treatment changed from surgery to the organ-preserving treatment maintaining laryngeal function (1). (Chemo)radiation is preferred as primary treatment because the swallowing and speech function are saved and the survival is similar to primary total laryngectomy (PTL) (2). Unfortunately, recurrent or persistent LC occurs in approximately one-third of the patients after primary non-surgical treatment (2). The last treatment option in these patients is a salvage total laryngectomy (STL) which goes along with several wound healing problems in up to 75% of the patients (2). Due to hypoxic, hypovascular and hypocellular effects from previously (chemo)radiation a successful wound healing after STL is challenging and result in pharyngocutaneous fistulas (PCF) in 30-75% of the patients (2). The pharyngeal wound closure in STL can be broken down and can result in a severe impairment of wound healing, prolonged hospitalization, necrotectomy, extra surgical reconstructions, impaired speech and compromised swallowing (1). To prevent these complications, transposition and layover of the pectoralis major muscle can be used in STL patients with advanced LC after previous (chemo)radiation.

In the literature, there are several risk factors identified for the development of PCF with an inaccurate tissue perfusion as a profound one (2). In the UMCG, indocyanine green dye (ICG) is used to detect abnormalities of the fundus in ophthalmology and to examine liver function as a standard care (3, 4). Also, in the UMCG recently a study is performed to detect hypoperfusion of the parathyroid glands after a thyroidectomy using ICG in intraoperative laser angiography (IOLA) (5). IOLA-ICG could detect poor tissue perfusion intraoperatively in real time (2). By identifying hypoperfusion of tissue during.

In PTL, STL or a neck dissection for LC a preventive onlay of pectoralis major muscle flap could be performed, whereas in patients with a sufficient perfusion this additional and mutilating surgery can be avoided. This could contribute to an improved personalized surgical treatment and less burden to the patient.

Aim of this explorative study is to validate IOLA-ICG as a robust method to identify hypoperfusion of both the pharyngeal mucosa and the skin of the neck during PTL or STL with or without (modified) radical neck dissection or during neck dissection for LC in patients with and without previous (chemo)radiation. This study is in collaboration with the Department of Maxillofacial Surgery and the Center for Optical Molecular Imaging Groningen. We hypothesize that IOLA-ICG determined hypoperfusion in patients who develop a PCF or wound complications within 4 weeks after operation.

#### Study objective

We hypothesize that IOLA-ICG determined hypoperfusion in patients who develop a PCF or wound complications within 4 weeks after operation.

#### Study design

During surgery within 10 minutes after laryngectomy and during wound closure for the skin

#### Intervention

By using IOLA-ICG, we will measure perfusion of pharyngeal mucosa and skin of the neck in 30 patients with PTL, STL or neck dissection for LC. The perfusion data will be correlated with development of PCF within 4 weeks after surgery. A receiver operation curve will be computed to determine sensitivity and specificity of IOLA-ICG for both hypoperfusion of the pharyngeal mucosa and skin of the neck.

# Contacts

#### Public

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# **Eligibility criteria**

## **Inclusion criteria**

- Proven carcinoma of the larynx
- > 18 years of age
- Undergo a PTL or STL with or without neck dissection or undergo neck dissection for LC
- Informed consent
- Patients are mentally competent

## **Exclusion criteria**

- Partial laryngectomy
- Pregnancy

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- Patients with known allergy against ICG or iodine/shellfish
- Patients with hyperthyroidism or thyroid gland adenoma
- Patients with dialysis dependent renal failure and/or kidney transplant

# Study design

## Design

Interventional
Other
Non controlled trial
Open (masking not used)
N/A , unknown

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2021
Enrollment:	30
Туре:	Anticipated

# **IPD** sharing statement

Plan to share IPD: No Plan description

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N/A
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# **Ethics review**

Positive opinion Date: Application type:

10-11-2020 First submission

# **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
NTR-new	NL9185
Other	METC Groningen : METC75862

# **Study results**

Summary results N/A