# Patent blue in laryngeal cancer

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON27148

**Source**
NTR

**Health condition**

laryngeal cancer, sentinel lymph node

### Sponsors and support

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

### Intervention

### Outcome measures

#### Primary outcome

After ex vivo confirmation that PB injected around LC in a laryngeal surgical specimen is not spreading into tissues beyond the tumor, the detection of SLN by a technique of injecting PB via a flexible laryngoscope using a working channel has to be tested.

#### Secondary outcome

We want to analyze the difference in PB spreading for detection of SLN in primary TL and salvage TL.

# Study description

### Background summary

Despite intensive treatment, prognosis of laryngeal cancer (LC) remains poor for patients with locally advanced disease. The recurrence rate of LC increases up to 50% in advanced T3-T4 tumors. The presence of lymph node metastases or the likelihood of a tumor spread to the lymph nodes are important for treatment selection. According to international guidelines, elective treatment of clinically and radiologically confirmed N0 regional lymph nodes is indicated in cT1-T3 supraglottic and T2b-T4b glottic cancer (without clinical signs of lymph node metastases).
In general, the sentinel lymph node (SLN) is the primary site which receives lymphatic drainage from metastasizing tumor tissue. Injection of patent blue (PB) around the tumor is used as a standard technique to visualize SLN during surgery in oral cancer, malignant breast cancer and melanoma. A confirmed negative SLN could lead to avoid unnecessary treatment of the neck and decrease complications like swallowing problems, fibrosis or lymphedema.
The aim of this in vivo pilot study (feasibility and validation) is to analyze the applicability and diagnostic accuracy of PB for detection of the SLN in (recurrent) LC in vivo by injection via the working channel of a flexible laryngoscope around the tumor. We hypothesize that PB injected via the laryngoscope with working channel, locates accurately at the SLN. This could result into a more accurate detection of the SLN and to a prevention of unnecessary neck dissections or irradiation.

### Study objective

We hypothesize that PB locates accurately at SLN by injecting PB around laryngeal tumor tissue.

### Study design

During surgery

### Intervention

By using a standard injection needle via the working channel of a CE-marked routinely used flexible laryngoscope, 0.5-1 ml PB will be injected around laryngeal tumor tissue at the beginning of a routinely performed TL under general anaesthesia.

# Contacts

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# Eligibility criteria

## Inclusion criteria

- proven carcinoma of the larynx
- > 18 yrs of age
- undergo a total laryngectomy with planned neck dissection.
- informed consent

## Exclusion criteria

- partial laryngectomy
- no planned neck dissection
- hypersensitivity for patent blue

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-09-2020 |

| | |
|---|---|
| Enrollment: | 10 |
| Type: | Anticipated |

### IPD sharing statement

**Plan to share IPD:** Undecided

**Plan description**
N/A

## Ethics review

Positive opinion

| | |
|---|---|
| Date: | 16-09-2020 |
| Application type: | 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 | NL8905 |
| Other | METC Groningen : METC74127 |

## Study results