

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

Nationaal Trial Register

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