

Patent blue in laryngeal cancer

Gepubliceerd: 16-09-2020 Laatste bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON27148

Bron

Nationaal Trial Register

Aandoening

laryngeal cancer, sentinel lymph node

Ondersteuning

Primaire sponsor: University Medical Center Groningen

Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

During surgery

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

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:	01-09-2020
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting

N/A

Ethische beoordeling

Positief advies	
Datum:	16-09-2020
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	NL8905

Register

Ander register

ID

METC Groningen : METC74127

Resultaten