Sentinel node Navigation surgery in early esophageal adenocarcinoma Patients

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25123

Source
NTR

Brief title
SNAP-II

Health condition

Early esophageal adenocarcinoma (high-risk T1b esophageal adenocarcinoma)

Sponsors and support

Primary sponsor: St. Antonius Hospital, Nieuwegein
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Outcome measures

Primary outcome

- Percentage of patients with a detectable sentinel node

- Concordance of pre-operative SPECT/CT and perioperative probe-based and ICG-based detection of sentinel nodes

- Number of resected sentinel nodes

- Ratio of number of dissected sentinel nodes and number of detected sentinel nodes on imaging

- Additional yield of ICG-based SN detection over technetium SN detection

Secondary outcome

- Procedure time of sentinel node navigation surgery

- Number of tumor-positive lymph nodes

- Number of resected (non-sentinel) lymph nodes

- Adverse events

Study description

Background summary

The objective of this study is to evaluate the feasibility, accuracy and safety of a sentinel node procedure using a radioactive tracer and lymphoscintigraphy in combination with indocyanine green (ICG) and near-infrared (NIR) technology in patients with high-risk T1b esophageal adenocarcinoma.

Study objective

Sentinel node navigation surgery in early esophageal adenocarcinoma is feasible and safe.

Study design

- Post-procedure follow-up until 30 days after surgery

Intervention

Sentinel node procedure using a radioactive tracer and lymphoscintigraphy in combination with indocyanine green and near-infrared technology.

Contacts

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Eligibility criteria

Inclusion criteria

1. Early esophageal adenocarcinoma, staged as T1 (confined to the mucosa or submucosa) with an indication for esophagectomy

2. Clinical condition allowing esophagectomy

3. Signed informed consent

Exclusion criteria

1. Neo-adjuvant (chemo)radiation therapy

2. Other primary tumor with a life-expectancy less than 5 years.

3. Known allergy for the radioactive tracer (technetium) or dye (indocyanine green)

4. Previous esophageal surgery interfering with the procedure

5. Comorbidity interfering with the procedures

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-07-2018
Enrollment:	5
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	16-07-2018
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	NL7167
NTR-old	NTR7390
Other	MEC-U : R17.028

Study results