ORACLE-study

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29249

Source
NTR

Brief title
ORACLE-study

Health condition

vroege slokdarmmaligniteit
behandeling
scopische lymfeklierverwijdering

early esophageal cancer
treatment
scopic lymph node dissection

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Amsterdam
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

- The number of lymph nodes dissected during thoracolaparoscopic lymph node dissection,

subdivided per lymph node station

- Number of tumor positive lymph nodes (lymph node station documented)

- Number of remaining lymph nodes in esophagectomy specimen, subdivided per lymph node station

Secondary outcome

- Procedure time of thoracolaparoscopic lymph node dissection

- Adverse events

Study description

Background summary

Esophageal adenocarcinoma (EAC) is increasing in the West1. EAC arises from Barrett's esophagus (BE). In BE, esophageal squamous epithelium progresses to adenocarcinoma through a multi-step transition consisting of intestinal metaplasia, low grade dysplasia (LGD), high grade dysplasia (HGD), and finally invasive cancer. This process can take several years up to decades. Patients with known BE are offered endoscopic surveillance. Recent developments, such as the spread of high definition endoscopes though the community, combined with a higher awareness and improved recognition of early (flat) lesions in Barrett's esophagus have led to an increase in detection of early EAC. Early EAC can be treated with endoscopic resection techniques, such as endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD)2. In case of low-risk early EAC (i.e., negative resection margins, histology showing a tumour confined to the mucosa, not poorly differentiated, and absence of vascular or lymphatic invasion), an endoscopic resection is considered to be a curative treatment, since in these lesions spread of tumour cells to the adjacent lymph nodes is highly exceptional (i.e.<2%)3. In case of submucosal invasion, poor differentiation grade, or lymphovascular invasion, the risk of concomitant lymph node metastasis is considered to be too high, and surgical esophagectomy is recommended in case of acceptable clinical condition4,5. In case of an irradical endoscopic resection (mainly in case of tumour positive vertical resection margins), an esophagectomy is needed to excise residual cancer. In case of a radical endoscopic resection, but a high risk EAC (for instance deeper submucosal invasion), the additional yield of subsequent esophagectomy is in the lymph node dissection, since the primary tumour has been radically resected by endoscopic means. In esophageal squamous cell carcinoma (ESCC), lymph node metastasis probably occurs even at an earlier stage than in Barrett's early cancer. In early ESCC, infiltration into the muscularis mucosae even without submucosal infiltration carries a significant risk for lymph node metastasis6,7. Surgical esophagectomy is a major surgical procedure associated with substantial morbidity, mortality and a temporary reduced quality of life (QoL). Reported series in the literature mention surgery-related morbidity rates of 40% and mortality of

2-4.6%, even in expert centers.2,8 Furthermore, QoL after esophagectomy is significantly affected: majority of patients experiences complaints related to upper-GI dysfunction, such as eating problems, gastroesophageal reflux or dumping syndrome. Long-term follow-up studies showed that it will take six to nine months to regain pre-operative QoL9,10,11. A retrospective study, which compared QoL between endoscopically and surgically treated patients, showed that the surgical group reported significantly more eating problems and gastroesophageal reflux, whereas the patients who were treated endoscopically showed more worry for cancer recurrence11. In early gastric cancer, endoscopic resection of early neoplastic lesions is a well studied, well accepted and frequently applied therapy, especially in the Far East. Similar to the esophagus, early gastric lesions can also be divided into low-risk and high-risk lesions. In high-risk lesions (e.g. in submucosally invading tumours, or in case of lymphovascular invasion), a surgical gastrectomy is considered the treatment of choice, even in case of an endoscopic R0 resection. Recently, the concept of endoscopic R0-resection followed by laparoscopic lymph node dissection without gastrectomy has gained interest. In a recent study by Abe et al., data of 21 patients were reviewed after ESD followed by laparoscopic lymph node dissection with preservation of the stomach in high risk early gastric cancer12. Of the 21 patients laparoscopic lymphadenectomy revealed lymph node metastasis in 2 patients. During a median follow-up of 61 months (including a follow up of 76 and 84 months in the two lymph node positive patients), no recurrent malignant disease was seen. We hypothesize that endoscopic radical resection of the tumor in combination with thoracolaparoscopic lymph node dissection might be of great value in the treatment of early esophageal carcinoma. This combination may lead to a tailored treatment and might be associated with less morbidity and mortality and a less impaired quality of life because of the less invasive character of the procedure and intact upper-GI functioning. We have studied the feasibility and safety of the thoracolaparoscopic lymph node dissection in human cadavers and swine and results are promising. However, to be sure about the feasibility of this procedure, we have to perform the procedure in humans. Therefore, we are conducting this study and in the future, a pilot-study will be conducted which will include patients that will undergo the thoracolaparoscopic lymph node dissection without concomitant esophagectomy.

Country of recruitment: the Netherlands

Study objective

Een minder invasief behandelalgoritme voor vroege slokdarmcarcinomen (ESD + scopische lymfeklierverwijdering) is net zo effectief en veilig als de huidige behandeling (oesofaguscardiaresectie met buismaagreconstructie).

Study design

perioperative

Intervention

scopic lymph node dissection of all lymph nodes involved in the drainage of the esophagus(experimental treatment), followed by esophagectomy (standard treatment) in one procedure/anesthesia.

Contacts

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Eligibility criteria

Inclusion criteria

- Esophageal cancer (EAC or ESSC)

- Clinical condition allowing surgical thoracolaparoscopic lymph node dissection and subsequent esophagectomy

- Signed informed consent

Exclusion criteria

- Neo-adjuvant (chemo)radiation therapy

- Comorbidity interfering with the procedures

- Unable to provide signed informed consent

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:	Pending
Start date (anticipated):	01-01-2014
Enrollment:	5
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-01-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40220
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4197
NTR-old	NTR4348
CCMO	NL46988.018.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40220

Study results

Summary results
N/A