ISCON trial - Laparoscopic ISchemic CONditioning prior to esophagectomy in patients with esophageal cancer and arterial calcifications

Published: 27-03-2019
Last updated: 12-04-2024

Assess the safety and feasibility of laparoscopic ISCON 12-18 days prior to esophagectomy for esophageal cancer in patients with arterial calcifications.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON50061

Source
ToetsingOnline

Brief title
ISCON trial

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Esophageal cancer, Esophagectomy, Ischemic conditioning

Outcome measures

Primary outcome

all complications grade 2 and higher (Clavien-Dindo classification) occurring during or after operation 1 (laparoscopic ISCON) and before operation 2 (esophagectomy).

Secondary outcome

secondary outcomes with regard to operation 1 (laparoscopic ISCON) are the duration of the procedure, blood loss, day of discharge postoperatively and grade 1 complications. Secondary outcomes with regard to operation 2 (esophagectomy) are anastomotic leakage rate, all other grade *3b complications and 30 day mortality. Further secondary endpoints are the induction of angiogenesis by biomarkers of microcirculation and redistribution of blood flow by measurement of indocyanine green (ICG) fluorescence angiography.

Study description

Background summary

Anastomotic leakage is the most important surgical complication following esophagectomy for esophageal cancer, leading to increased morbidity and mortality. A major cause of leakage is impaired healing due to ischemia of the gastric tube that is used for reconstruction of the gastrointestinal tract. Calcifications of the aorta or stenosis of the celiac trunk on pre-operative CT

scan have been shown to be associated with an increased risk of anastomotic leakage. So far, no individualized treatment has been initiated for this selected group of patients. Laparoscopic ischemic conditioning (ISCON) of the gastric tube aims to increase perfusion at the anastomotic site by redistribution of the gastric blood flow and/or induction of angiogenesis. This is achieved by occlusion of the supplying gastric arteries except for the right gastroepiploic artery during a separate intervention prior to esophagectomy. Of note, these arteries would also be occluded during conventional esophagectomy, but with laparoscopic ISCON they are occluded at an earlier moment in time during a separate intervention. Retrospective studies have demonstrated the safety of this technique. Prospective studies have not yet been performed.

Study objective

Assess the safety and feasibility of laparoscopic ISCON 12-18 days prior to esophagectomy for esophageal cancer in patients with arterial calcifications.

Study design

Two center phase II prospective single-arm safety and feasibility trial.

Intervention

Laparoscopic ISCON followed by esophagectomy after an interval of 12-18 days.

Study burden and risks

the additional burden for the patient consists of an extra operation of approximately 40 minutes during which laparoscopic ISCON will be performed, prior to the planned esophagectomy. We would classify the current study as medium risk. Potential benefits in comparison to current standard treatment are a reduced risk of anastomotic leakage and severity of anastomotic leakage. Potential risks are complications following operation 1 (laparoscopic ISCON). Mainly, based upon prior experience, we expect gastroparesis to occur in 25% of patients. Patients with gastroparesis have an increased risk of aspiration and will require a stomach emptying by nasogastric tube and nasojejunal tube feeding till the performance of operating 2 (esophagectomy).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with resectable esophageal carcinoma (cT1-4a, N0-3, M0) with *major calcifications* of the thoracic aorta (UCS) or stenosis of the celiac axis (modified NASCET score) on preoperative CT scan, who are planned to undergo transthoracic of transhiatal esophagectomy.

Exclusion criteria

Not able to undergo study treatment (surgery).
Metastatic disease (M1)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2020
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	27-03-2019
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-03-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	20-08-2020
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL67819.041.18