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Goedgekeurde aanvraag gegevens ten behoeve van wetenschappelijk onderzoek
DUCA201512

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Titel onderzoek
Optimal surgical treatment for GE-junction tumors: gastrectomy or esophagectomy.

Contactpersoon
S.S. Gisbertz, Chirurg, Amsterdam UMC, locatie AMC

Aanvragersgroep
M.I. van Berge Henegouwen, Chirurg, Amsterdam UMC, locatie AMC
S.S. Gisbertz, Chirurg, Amsterdam UMC, locatie AMC
E. Jezerskyte, arts-onderzoeker Amsterdam UMC, locatie AMC
A.C. Mertens, arts-onderzoeker Amsterdam UMC, locatie AMC

Beschrijving onderzoek
One of the most difficult surgical decision making is to decide on the operative strategy for junctional carcinoma's. One can either perform a total gastrectomy or an esophagectomy. No evidence exists which operation is the preferred strategy in terms of short term-outcome and survival.
Due to a small study population from the data we received from 2011-2016 we would like to include the data from 2017 as well as the data on short and long term survival till 2016.

Onderzoeksvraag:
Does an esophagectomy cause less surgical morbidity than a gastrectomy for cancer of the esophago-gastric junction?

Primary outcome:
- Survival (short/long term)
- Mortality (in-hospital and 30-days)

Secondary outcome:
- Reinterventions
- Length of ICU-stay and hospital stay
- Other morbidity
- Readmissions
- Anastomotic dehiscence
- Quality of surgery
    - R0-resection rate
    - Circumferential resection margin
    - Harvested lymph nodes (tumor negative and tumor positive)

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Onderzoeksopzet:
A retrospective comparative cohort study of prospectively collected data from the Dutch upper-GI cancer audit will be performed. Patients with an adenocarcinoma or squamous cell carcinoma of the gastrointestinal junction who underwent surgery in the period between January 2011 to December 2017 will be included and patients following a gastrectomy or esophagectomy will be compared. Transhiatal (laparoscopy and laparotomy) and transthoracic (thoracolaparoscopy and thoracotomy/laparotomy) esophagectomies will be analyzed separately, as well as open and minimally invasive techniques. Parameters to be recorded will be: baseline characteristics, clinical data of the postoperative course (morbidity and mortality), survival and pathology results including lymph node count and R0-resection rate.

Onderzoekspopulatie:
Patients undergoing a gastrectomy or esophagectomy due to an adenocarcinoma or squamous cell carcinoma of the gastrointestinal junction between 1-1-2011 and 1-1-2018.

Statistiek:
Statistical analysis will be performed with SPSS 25.0 software (SPSS, Inc., Chicago, IL, USA). A Mann-Whitney U test or $\chi 2$-test will be used as indicated to compare groups. A value of $p < 0.05$ will be considered statistically significant. No formal power analysis or sample size calculation will be performed, but all inclusions in the DUCA will suffice for an exploratory study. Survival will be analyzed through Kaplan-Meier analysis with log-rank testing.

Beoogde publicatie
Optimal surgical treatment for GE-junction tumors: gastrectomy or esophagectomy.