Laparoscopic versus Open Gastrectomy: a multicenter randomized controlled trial

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21049

Source
NTR

Brief title
LOGICA-trial

Health condition

Gastric Cancer, Gastrectomy, Laparoscopy
Maagkanker, Maagresectie, Laparoscopie

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: ZonMW
Johnson & Johnson

Intervention

Outcome measures

Primary outcome

Hospital stay

Secondary outcome

Post-operative morbidity

Mortality

Readmissions

Oncologic outcome

Quality of life

Cost-effectiveness

Study description

Background summary

For gastric cancer patients, surgical resection with en-bloc lymphadenectomy is the cornerstone of multi-modality treatment. Open gastrectomy has long been the preferred surgical approach worldwide. However, this procedure is associated with considerable morbidity. Several meta-analyses have shown an advantage in short-term outcomes of laparoscopic gastrectomy compared to open procedures, with similar oncologic outcomes. However, these studies were predominantly based on Asian populations, which show significant differences compared to Western populations. In this randomized controlled trial laparoscopic and open gastrectomy are compared in a Western population.

The design of the study is a non-blinded multicenter prospectively randomized controlled, superiority trial. Patients (≥18 years) with histologically proven, surgically resectable (cT1-4a, N0-3b, M0) gastric adenocarcinoma and European Clinical Oncology Group performance status 0, 1 or 2 are eligible to participate in the study after obtaining informed consent. Patients (n = 210) will be informed and included at the surgical outpatient department at one of the eight participating Dutch investigational centers and randomized to either laparoscopic or open gastrectomy. The primary outcome of this study is post-operative hospital stay (days).

This is the first randomized controlled trial comparing laparoscopic and open gastrectomy for resectable gastric cancer in a Western population. The hypothesis is that laparoscopic gastrectomy will result in a lower post-operative burden by means of shorter post-operative hospital stay. Secondarily that laparoscopic gastrectomy is hypothesized to be associated with lower post-operative morbidity and readmissions, higher cost-effectiveness, and better post-operative quality of life, with similar mortality and oncologic outcomes, compared to

open gastrectomy. The study starts on 1 December 2014. Inclusion and follow-up will take three and five years respectively. Short-term results will be analyzed and published after discharge of the last randomized patient.

Study objective

Laparoscopic gastrectomy will result in a lower post-operative burden by means of shorter post-operative hospital stay

Study design

- Hospital stay (in days). Timepoint: on discharge

- Post-operative morbidty (Clavien-Dindo). Timepoint: 5 years post-operative

- Mortality (1- and 5-year disease free survival rate). Timepoint: 5 years post-operative

- Readmissions (number of). Timepoint: 5 years post-operative

- Oncologic outcome (lymph nodes harvested and R0-resection rate). Timepoint: pathology report

- Quality of life (SF-36, EORTC QLQ-30 and EORTC QLQ-STO22). Timepoint: 6 weeks, 6, 12, 24, 36, 48, 60 months post-operative

- Cost-effectiveness (direct medical cost related to both strategies). Timepoint: 5 years post-operative

Intervention

Laparoscopic or Open procedure for Total or Distal Gastrectomy

Contacts

Public
L. Haverkamp
Dept. of Surgery, G04.228
University Medical Center Utrecht
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)88-755 8074
Scientific
L. Haverkamp

Dept. of Surgery, G04.228
University Medical Center Utrecht
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)88-755 8074

Eligibility criteria

Inclusion criteria

• Histologically proven adenocarcinoma of the stomach

• Surgically resectable (cT1-4a, N0-3b, M0) tumor

• Age ≥ 18 years

• ECOG performance status 0,1 or 2.

• Written informed consent

Exclusion criteria

Exclusion criteria

• Siewert type I esophago-gastric junction tumor

• Prior gastric surgery

• Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	210
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 47143
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4616
NTR-old	NTR4767
CCMO	NL47444.041.14
OMON	NL-OMON47143

Study results

Summary results

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Japanese Gastric Cancer Association. Japanese gastric cancer treatment guidelines 2010 (ver. 3). Gastric Cancer. 2011 Jun;14(2):113-23. doi: 10.1007/s10120-011-0042-4. PubMed PMID: 21573742

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