Laparoscopic versus Open Gastrectomy - A multicenter prospectively randomized controlled trial

Published: 08-10-2014
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To evaluate the benefits, risks and costs of laparoscopic gastrectomy as an alternative to open gastrectomy (gold standard) as treatment for gastric cancer in a Western population.

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

Summary

ID

NL-OMON47143

Source
ToetsingOnline

Brief title
LOGICA

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal therapeutic procedures

Synonym
Gastric cancer, gastric carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Heelkundige Specialismen
Source(s) of monetary or material Support: ZonMW subsidie toegekend,Johnson & Johnson

Intervention

Keyword: Cancer, Gastrectomy, Laparoscopy, Open

Outcome measures

Primary outcome

Primary outcome is postoperative hospital stay (days).

Secondary outcome

Secondary outcomes are cost-effectiveness, oncologic outcomes, postoperative

morbidity, mortality, and quality of life.

Study description

Background summary

Gastric cancer is a life-threatening disease with an incidence of 2.000 in the Netherlands. Surgical resection is the cornerstone of curative treatment. In the Netherlands this procedure is mainly performed by open surgery, whereas our recent meta-analysis of cohort studies showed that laparoscopic gastrectomy is associated with reduced intraoperative blood loss, reduced postoperative complications and shorter hospital stay. These benefits were at the cost of longer operative time. However, thus far all studies were performed in an Asian population containing a large percentage of T1-2 tumors. There is no RCT in a Western population with locally advanced gastric cancer. In the Netherlands experience with laparoscopic gastrectomy has increased in the last years, with now more than 5 centers performing this type of operation on a routine basis. We have trained this technique to 30 surgeons visiting our Minimally Invasive Gastrectomy course in the past 2 years.

Study objective

To evaluate the benefits, risks and costs of laparoscopic gastrectomy as an alternative to open gastrectomy (gold standard) as treatment for gastric cancer in a Western population.

Study design

Multicenter prospectively randomized controlled trial

Intervention

Laparoscopic versus open gastrectomy.

Study burden and risks

Patients will undergo either laparoscopic gastrectomy (experimental arm) or the conventional open gastrectomy (gold standard). Tumor biopsies will be collected pre-operatively. Blood samples will be drawn preoperative, at baseline and on postoperative day 1 and 2. Patients are required to fill out quality of life questionnaires (preoperatively and <5 days, 6 weeks, 3, 6 and 9 months, and yearly up to 5 years postoperatively). Laparoscopic gastrectomy was demonstrated to be safe in our own series of 30 patients treated in the UMC Utrecht as well as in our recent meta-analysis of the literature.

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

• Histologically proven gastric adenocarcinoma
• Surgically resectable (cT1-4a, N0-3b, M0) tumor
• Mentally capable patient
• Age >= 18
• European Clinical Oncology Group (ECOG) performance status 0,1 or 2
• Written informed consent

Exclusion criteria

• Siewert type I junction tumor (tumor located <=5 cm proximal from the esophagogastric junction)
• Pregnant women
• Mentally incompetent patients
• Non-elective surgery
• Previous gastric resection or recurrent gastric cancer

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	19-02-2015
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2014
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-02-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-05-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-06-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-08-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	17-11-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-01-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	19-04-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	21-03-2017

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-07-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-11-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	04-04-2019
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

ID: 21049
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
ClinicalTrials.gov	NCT02248519
CCMO	NL47444.041.14
OMON	NL-OMON21049