STOMACH trial: Surgical Technique, Open versus Minimally-invasive gastrectomy After CHemotherapy

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

Summary

ID

NL-OMON47811

Source
ToetsingOnline

Brief title
STOMACH trial

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Gastric cancer, gastric carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting NutsOhra

Intervention

Keyword: Gastric cancer, Laparoscopy, Minimally-invasive, Total Gastrectomy

Outcome measures

Primary outcome

As posed in the background information, it is imperative that a new surgical technique has similar results with regard to quality of oncological resection. The primary endpoint in the STOMACH trial is therefore quality of concological resection, as measured by radicality of surgery, the number of resected lymph nodes and the number of resected lymph nodes stations.

Secondary outcome

Secondary endpoint in the STOMACH trial consist of postoperative complications according to the Clavien-Dindo classification, mortality, duration of hospital admission and 3-year survival. Along with quality of life as measured with Patient Related Outcome Measures (PROMs); the EQ-5D, and EORTC-QLQ30 and STO22 questionnaires. Furthermore, a cost-efficiciency analysis will be conducted.

Study description

Background summary

Aim of this prospective randomised, multi-center trial is to compare open gastrectomy with minimally invasive gastrectomy for gastric cancer in patients that received neoadjuvant chemotherapy.
Laparoscopic surgery has been shown to provide important advantages in comparison with open procedures in the treatment of several malignant diseases, such as less peri-operative blood loss, faster patient recovery and shorter hospital stay. All while maintaining similar results with regard to tumour resection margin and oncological survival. In gastric cancer the role of laparoscopic surgery remains unclear.

Several studies have focussed on laparoscopic versus open gastrectomy. These studies are predominantly conducted in Asian countries, where incidence of gastric cancer is higher. The screening program in Japan has enabled early detection and treatment of gastric carcinomas. As such, tumour stages are lower at the time of diagnosis compared to Western countries. Therefore it is difficult to translate the results of Asian studies to the Western population. Only a few Western studies were conducted that compare laparoscopic and open approaches for gastric cancer. An important previous finding is that laparoscopic gastrectomy showed similar results to open gastrectomy with regard to quality of oncological resection and survival, whereas patient recovery was faster. The studies were, however, small and underpowered. Moreover, the studies focussed on distal gastrectomy rather than total gastrectomy.

Current recommended treatment for gastric cancer consists of radical resection of the stomach, combined with lymfadenectomy. The extent of lymfadenectomy is considered a marker for radicality of surgery and quality of care. Therefore, It is imperative that a new surgical technique, such as minimally-invasive total gastrectomy, should be non-inferior with regard to radicality and lymph node yield.

The STOMACH trial aims to establish the optimal surgical technique in the treatment of gastric cancer, the open approach or the minimally-invasive approach

Study objective

Goal of the STOMACH trial (Surgical Technique, Open versus Minimally-invasive gastrectomy After CHemotherapy) is to establish the optimal surgical strategy in the treatment of gastric cancer. A minimally-invasive total gastrectomy will be compared to a conventiona; 'open' resection.

Study design

STOMACH is a randomized controlled, double blinded, parallel, international multi-center, non-inferiority trial. Patients with gastric cancer and an indication for total gastrectomy after neoadjuvant therapy will be randomised in two groups; open gastrectomy versus minimally invasive gastrectomy. Randomisation will be stratified per participating center. Patients will be enrolled from 6 international hospitals.
In order to obtain 90% power and a significance level of 0,05 a total of 96 patients are to be included, 48 allocated to each arm

Intervention

The intervention to be researched in the STOMACH trial is minimally-invasive total gastrectomy. This will be compared to the control intervention,

conventional 'open' total gastrectomy.
In minimally-invasive total gastrectomy the stomach is operated on via 5 small incisions. Trocars are inserted in these incisions to allow for insertion of a camera and instruments in the abdomen. After stomach is resected, one of the incisions is slightly enlarged in order to remove the specimen from the abdomen

Study burden and risks

The STOMACH trial compares a minimally-invasive gastrectomy with a conventional 'open' resection. Research will show whether a minimally-invasive technique is feasible in gastric resection for cancer. Long term results regarding both techniques will establish the optimal surgical strategy, especially disease-free survival.
A minimally-invasive procedure usually lasts longer than a conventional procedure. Minimally-invasive techniques are not associated with increased risk of complications. Both techniques are associated with normal risks associated with surgery. Sometimes a minimally-invasive procedure does not seem feasible, for example due to adhesions. The operation will be converted to a conventional 'open' approach

It could be possible that an extra venous puncture is necessary (max 3 times) for research of immunology.

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

Age equal to or above 18 years. Patients with primary adenocarcinoma of the stomach, with an indication for total gastrectomy. The tumour is considered surgically resectable (T1-2, N0-1, M0). Patients have received neoadjuvant chemotherapy (all therapeutic regimens are allowed). Patients are able to give informed consent.

Exclusion criteria

Patients with previous or coexisting cancer. Patients who have had previous surgery of the stomach. Patients who are not deemed suitable for minimally-invasive surgical techniques by the operating surgeon, Patients with an ASA-score (American Society of Anaesthesiologists) of 4 or higher

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-03-2015
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT02130726
CCMO	NL51293.029.14