Treatment of limited Oligo Metastatic disease in Esophageal and Stomach carcinoma; TOMES trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON52125

Source
ToetsingOnline

Brief title
Treatment of limited Metastatic disease in Esophageal and Stomach carcinoma

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
stomach and esophagus cancer, upperGi cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cancer, esophagus, oligo metastases, stomach

Outcome measures

Primary outcome

progression free survival

Secondary outcome

-safety

-quality of life

- overall survival

- whether ctDNA can help us better select the right patients in the future who

will benefit from this treatment

Study description

Background summary

In previous research it seems that a more intensive treatment of gastric or esophageal cancer, including limited metastases, can lead to a better survival. However, these previous studies were done in small patient groups, which were very different from each other. Therefore, it is currently unclear whether 1) this more intensive treatment has real added value and 2) which patients can benefit from this treatment and who cannot. Through this research, we want to see whether we can find a group of patients who would benefit from this by mapping various tumor characteristics, as well as blood values.

Study objective

The aim of this study is to evaluate whether intensive treatment of gastric and esophageal cancer with limited metastases can lead to a better survival. We also want to evaluate whether factors can be found that can predict which patients will benefit from this more intensive treatment before starting treatment. At present, the standard treatment in the Netherlands for metastatic gastric and esophageal cancer consists of chemotherapy with the aim of alleviating any symptoms and, if possible, prolonging life. In this study, we

want to evaluate whether, in addition to chemotherapy, the removal of the gastric or esophageal cancer, including the metastases, leads to a longer survival than if only chemotherapy were given.

Study design

The first step is chemotherapy treatment. This is the standard treatment for people with metastatic esophageal and stomach cancer in the Netherlands. Which chemotherapy is determined by the internist-oncologist. During and after chemotherapy, scans are performed to check whether the cancer has not grown despite chemotherapy:
- If the cancer has grown, the study will end for those patients.
- If the disease has remained the same or has decreased after chemotherapy, the following steps will be followed

In case of stomach cancer:
- After a waiting period of at least 6 weeks during which no new metastases are seen on scans, it will remove the stomach cancer as well as the metastases.
- To remove the stomach cancer, an operation will take place in which all or part of the stomach (depending on the location of the cancer) is removed.
- There are different ways of treatment for removing the metastases. The choice depends, among other things, on where the metastasis is located. If several methods are possible, the least intrusive method will be chosen. The treatment options from which you can choose are: radiation (radiotherapy), ablation (puncturing the metastasis with a thin radiofrequency needle with which the metastasis can be heated and killed) or surgery.
- The order in which the gastric cancer or metastases are treated depends on the methods of treatment.

In case of esophageal cancer:
- approximately 6 weeks after chemotherapy, treatment for the esophageal cancer will be started if no new metastases are visible on scans. This treatment consists of a combination of radiation and chemotherapy (chemoradiation).
- After a waiting period of about 6 weeks after the end of the chemoradiation, the metastases and esophageal cancer are examined again.
- If no new metastases have arisen during the time of the above treatment, a visual examination of the esophagus will be used to determine whether there is still cancer in the esophagus after radiotherapy.
- If there is no more cancer in the esophagus, the metastases will be removed. There are various ways of treatment available to remove the metastases. The choice depends, among other things, on where the metastasis is located. If several methods are possible, the least intrusive method will be chosen. The treatment options from which you can choose are: radiation (radiotherapy), ablation (puncturing the metastasis with a thin radiofrequency needle with which the metastasis can be heated and killed) or surgery.
- If there is still cancer in the esophagus, surgery will be performed to remove the esophageal cancer. In addition, the metastases are removed, as

explained above.
- The order in which the treatment of the gastric cancer or the metastases take place depends on the methods of treatment.

Study burden and risks

In this study, patients initially receive the standard treatment, namely palliative chemotherapy. Only in the case of a good response are patients eligible for local treatment of the primary tumor and metastases. The additional burden and risks of this study are therefore in this phase of treatment. These are the standard risks associated with surgery on the esophagus or stomach and treatment of the metastases.

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 cT2-4aN0-2 adenocarcinoma carcinoma of the oesophagus, gastroesophageal junction or stomach.
• histologically proven metastases from esophageal or gastric cancer or if histologic biopsy is not possible, radiological images are highly suspicious for metastases
• Maximum of 3 metastases in one organ OR M1 lymph node metastasis restricted to one region (brain metastases are allowed)
• Resectable primary tumor.
• Metastases eligible for adequate local treatment.
• good performance status (WHO performance status 0-2) (appendix I).
• ASA 1-2 (appendix II).
• written informed consent.
• age >= 18
• fit to receive palliative systemic treatment

Exclusion criteria

• pregnancy, lactating female
• peritoneal metastases or positive cytology from abdominal washings.
• patients participating in other trials that would interfere with the implementation of this protocol.
• Patients with N3M1 disease
• Unable or unwilling to undergo systemic palliative treatment

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2022
Enrollment:	73
Type:	Anticipated

Ethics review

Approved WMO Date:	21-07-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	05-12-2022
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	NL78680.031.21