Treatment of PERitoneal dissemination in Stomach Cancer patients with cytOreductive surgery and hyperthermic intraPEritoneal chemotherapy: the PERISCOPE II study

Published: 14-11-2016
Last updated: 30-01-2025

This study has been transitioned to CTIS with ID 2023-510159-53-01 check the CTIS register for the current data. The primary aim of this study is to compare the overall survival between gastric cancer patients with limited peritoneal carcinomatosis...

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

Summary

ID

NL-OMON53132

Source
ToetsingOnline

Brief title
PERISCOPE II study

Condition

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

Synonym
Adenocarcinoma of the stomach, gastric cancer

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W,Onderzoeksfonds;KWF;deelnemende centra zelf. De financiering voor de PERISCOPE II studie is onderdeel van een lopende aanvraag voor voorwaardelijke toelating tot het basispakket van de Zorgverzekeringswet.

Intervention

Keyword: Gastric adenocarcinoma, HIPEC, Peritonitis carcinomatosa

Outcome measures

Primary outcome

The study endpoint is overall survival. The hypothesis is that the median overall survival of the patients treated according to protocol in the experimental arm is 12 months, as compared to a median overall survival of 4 months in the standard arm.

Secondary outcome

- To compare the progression free survival between gastric cancer patients with limited peritoneal carcinomatosis and/ or tumour positive peritoneal cytology treated with gastrectomy, cytoreductive surgery and HIPEC and those treated with the current standard treatment, i.e. palliative systemic chemotherapy.
- To study treatment-related toxicity in gastric cancer patients with limited peritoneal carcinomatosis and/ or tumour positive peritoneal cytology treated with gastrectomy, cytoreductive surgery and HIPEC.
- To compare the costs and health benefits of a gastrectomy in combination with cytoreductive surgery and HIPEC, to the costs and health benefits of standard palliative systemic chemotherapy in patients with limited peritoneal

carcinomatosis and/ or tumour positive peritoneal cytology.

- To identify genetic profiles related to tumour response in gastric cancer

patients with limited peritoneal carcinomatosis and/ or tumour positive

peritoneal cytology. (Optional)

Study description

Background summary

For gastric cancer patients with peritonitis carcinomatosa palliative systemic chemotherapy is the standard treatment in the Netherlands. There are no potentially curative treatment options. Peritoneal carcinomatosis, in contrast to lymphatic and haematogenous dissemination, should be regarded as locoregional extension of disease. Administering chemotherapeutic drugs directly into the peritoneal cavity has an advantage over systemic chemotherapy since high concentrations of cytotoxic drugs can be delivered directly into the peritoneal cavity with little systemic toxicity. The combination of intraperitoneally administered chemotherapy with a total gastrectomy and peritonectomy has shown promising results in gastric cancer patients in Asia. As with other gastric cancer issues, the results obtained in Asian patients can not be extrapolated directly to Western patients.

Study objective

This study has been transitioned to CTIS with ID 2023-510159-53-01 check the CTIS register for the current data.

The primary aim of this study is to compare the overall survival between gastric cancer patients with limited peritoneal carcinomatosis and/ or tumour positive peritoneal cytology treated with gastrectomy, cytoreductive surgery and hyperthermic intra-peritoneal chemotherapy (HIPEC) and those treated with the current standard treatment, i.e. systemic palliative chemotherapy.

Study design

This is a randomised controlled multicentre two-armed phase III trial.

Intervention

Patients will be randomised (1:1) between palliative systemic chemotherapy (standard treatment) and gastrectomy combined with cytoreductive surgery and

HIPEC (experimental treatment).

Study burden and risks

In the experimental treatment arm patients will be admitted for surgery. Postoperative complications may occur (e.g. bleeding, wound infection, pneumonia, ileus, anastomotic leakage). Also, toxicities related to the chemotherapeutic agents can occur. In both groups a maximum of 8 blood samples will be taken. All patients will be asked to complete quality of life questionnaires at 6 moments in time. All patients will be seen at the outpatient clinic once every 3 months for 1.5 years, and every 6 months thereafter.

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 >= 18 years
- cT3-cT4 adenocarcinoma (or undifferentiated carcinoma) of the stomach, considered to be resectable
- Limited peritoneal carcinomatosis (PCI <7) and/ or tumour positive peritoneal cytology (proven by laparoscopy or laparotomy)
- Absence of disease progression during systemic treatment (prior to inclusion)
- WHO performance status 0-2
- Adequate bone marrow, hepatic and renal function

Exclusion criteria

- Distant metastases or small bowel dissemination
- Recurrent gastric cancer
- Prior resection of the primary gastric tumour
- Non-synchronous peritoneal carcinomatosis
- Current other malignancy (other than cervix carcinoma and basalioma)
- Hepatitis B or C, known HIV infection or an uncontrolled infectious disease
- Recent myocardial infarction (< 6 months) or unstable angina
- Uncontrolled diabetes mellitus
- Pregnancy or breast feeding
- Any medical condition that is considered to interfere with study procedures and/or would jeopardize safe treatment
- Known hypersensitivity for any of the applied chemotherapeutic agents and/or their solvents

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	06-11-2017
Enrollment:	226
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Oxaliplatin
Generic name:	Oxaliplatin
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Taxotere
Generic name:	Docetaxel
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	14-11-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-07-2017
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	14-09-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-05-2018
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	15-06-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	27-09-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-01-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-10-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	11-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	09-07-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-10-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-03-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-09-2022
Application type:	Amendment

Review commission:	METC NedMec
Approved WMO Date:	11-03-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-05-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	23-07-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-07-2024
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
EU-CTR	CTIS2023-510159-53-01
EudraCT	EUCTR2015-005695-15-NL
ClinicalTrials.gov	NCT03348150
CCMO	NL56123.031.15

Study results

Date completed: 17-09-2024

Summary results
Trial ended prematurely