Detection of aneuploidy in cell free DNA to improve the sensitivity of diagnostic peritoneal lavage in gastric cancer

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To assess whether ctDNA can be detected in PLF using the mFAST-SeqS method in a prospective cohort of patients with GC/GEJC who undergo a DLS.

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

Summary

ID

NL-OMON57074

Source
ToetsingOnline

Brief title
Detection of aneuploidy in cell free DNA in gastric cancer

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
gastric cancer, gastric carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NVGE (Nederlandse Vereniging voor Gastro-enterologie)

Intervention

Keyword: cfDNA, Gastric cancer

Outcome measures

Primary outcome

The primary endpoint of this study is ability the mFast-SeqS technique to

detect ctDNA in patients with GC/GEJC.

Secondary outcome

Determine the test characteristics of the mFAST-SeqS method in PLF by analyzing

non-cancer and tumor-positive controls;

Concordance of detection rate of peritoneal dissemination between aneuploidy

and conventional methods (visual inspection and cytology);

Study description

Background summary

To ensure the appropriate treatment strategy for gastric cancer, various methods are employed to determine clinical disease stage. Peritoneal metastases are common in gastric/GEJ cancer, but accurately detecting these peritoneal metastasis using conventional imaging techniques remains challenging. To increase the sensitivity of staging when gastric/GEJ cancer appears resectable on CT imaging, a diagnostic peritoneal staging laparoscopy (DLS) is performed. During DLS, the abdominal cavity is inspected for the presence of macroscopic peritoneal metastasis. Furthermore, a peritoneal lavage with saline is performed, and the collected peritoneal lavage fluid (PLF) is examined by a pathologist for the presence of cancer cells. However, the sensitivity of this cytological evaluation is limited, and as a result of false negative results, patients currently unjustly undergo treatment with curative intent, exposing them to the risks and side-effects of surgery and intensive perioperative chemotherapy. A more sensitive technique to detect peritoneal metastases during staging would lead to better personalized treatment; less toxic palliative treatment, or more intensive peritoneum-directed therapy in a trial setting in selected patients.
A more sensitive diagnostic tool to detect peritoneal metastasis compared to

conventional cytology and imaging techniques may be the detection of ctDNA. One way to detect ctDNA is by assessing aneuploidy, as its presence reflects the fraction of circulating tumor DNA within cell-free DNA.

Study objective

To assess whether ctDNA can be detected in PLF using the mFAST-SeqS method in a prospective cohort of patients with GC/GEJC who undergo a DLS.

Study design

prospective biomarker study

Study burden and risks

Collection of additional peritoneal lavage fluid is considered safe, and there are no additional risks to collection of additional peritoneal lavage fluid, or blood withdrawal.The risks associated with participation for both gastric-/gastroesophageal junction cancer patients as non-cancer controls are considered negligible. All safety measures and procedures will be performed according to local guidelines.

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

GC/GEJC patients:
o Patients who will undergo DLS for GC/GEJC;
o Age >=18 years old;
o Written informed consent according to the ICH-GCP and national/local regulations.

non-cancer controls:
o Operable patients who will undergo a planned diagnostic laparoscopy for a benign indica-tion bariatric or gallbladder disease);
o Age >=18 years old;
o Written informed consent according to the ICH-GCP and national/local regulations.

Exclusion criteria

GC/GEJC patients:
o Language difficulty, dementia or altered mental status prohibiting the under-standing and giving of informed consent.

non-cancer controls:
o Active inflammation or infection;
o Subjects with previous malignancies are excluded unless a complete remission was achieved at least 5 years prior to study entry (exceptions include but are not limited to, non-melanoma skin cancers; in situ bladder cancer, or in situ co-lon cancers; in situ cervical cancers/dysplasia; or breast carcinoma in situ).

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	62
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-10-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NCT06308510
CCMO	NL86198.078.24