The prognostic value of occult peritoneal tumor cells, detected by ddPCR for KRAS, in patients with (borderline) resectable pancreatic cancer

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To add 36 benign control patients to the Expect study to investigate whether detection of a KRAS mutation by ddPCR in peritoneal fluid is truly specific for pancreatic cancer.

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON51142

Source ToetsingOnline

Brief title EXPECT study

Condition

• Miscellaneous and site unspecified neoplasms benign

Synonym metastases, pancreatic cancer

Research involving Human

Sponsors and support

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

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Intervention

Keyword: Cancer, ddPCR, KRAS, Occult, Pancreastic, Peritoneal

Outcome measures

Primary outcome

Presence or absence of KRAS mutation in peritoneal fluid.

Secondary outcome

Study description

Background summary

In patients with pancreatic ductal adenocarcinoma (PDAC), the presence of occult peritoneal tumor cells (OPTC) at the time of resection is associated with a worse overall and recurrence free survival. It is unclear what is the best method to accurately diagnose OPTC in patients with PDAC. KRAS is the predominant mutation in PDAC and present in over 90% of the patients. Digital droplet PCR, ddPCR is, a relatively new and promising method to detect mutant DNA. It is able to reliably detect low amounts of DNA and therefore a very sensitive method for the detection of low abundant targets. The Expect study has been conducted to (i) detect the presence of KRAS-mutated DNA in the peritoneal fluid of patients with (borderline) resectable PDAC using ddPCR and (ii) to investigate whether the presence of KRAS-mutated DNA in the peritoneal fluid was related to the patient*s prognosis, in terms of overall survival and disease free survival.

Study objective

To add 36 benign control patients to the Expect study to investigate whether detection of a KRAS mutation by ddPCR in peritoneal fluid is truly specific for pancreatic cancer.

Study design

Cohort study of 36 patients selected at the surgical outpatient clinic of OLVG. Laparoscopic cholecystectomy and obtainment of peritoneal fluid will be carried out in the BovenIJ Hospital. Molecular analysis of peritoneal fluid will be carried out at the pathology department of Amsterdam UMC.

Study burden and risks

Risks are negligible and the burden minimal.

Contacts

Public OLVG

Oosterpark 9 Amsterdam 1091AC NL **Scientific** OLVG

Oosterpark 9 Amsterdam 1091AC NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years)

Inclusion criteria

- Indication for laparascopic cholecystectomy

- Age > 18

Exclusion criteria

A medical history of cancer

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):	01-09-2021
Enrollment:	36
Туре:	Anticipated

Ethics review

Approved WMO	
Date:	30-07-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

4 - The prognostic value of occult peritoneal tumor cells, detected by ddPCR for KRA ... 23-06-2025

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

ССМО

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