Assessing stromal architecture with MR Elastography to predict cytotoxic treatment efficacy in pancreatic cancer (ASAP-study)

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Predict response to FOLFIRINOX treatment in patients with LAPC based on baseline stiffness values derived with MRE.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON52085

Source
ToetsingOnline

Brief title
ASAP

Condition

- Other condition

Synonym
Pancreatic carcinoma; Pancreatic cancer

Health condition

Pancreatic adenocarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerfonds

Intervention

Keyword: Elastography, MRE, Pancreas, PDAC

Outcome measures

Primary outcome

The main study parameter is the one-year progression free survival of patients with LAPC who received FOLFIRINOX. The research population will be divided into two groups, responders and non-responders. Responders are defined as patients who do not show tumour progression one year after the start of the treatment with FOLFIRINOX. The optimal cut-off value between high and low stiffness will be determined during this study between both groups. From this, the predictive value of MRE on FOLFIRINOX treatment efficacy will be determined.

Secondary outcome

The one and two-year overall survival rate of patients with LAPC who received FOLFIRINOX and its relation to the parameters measured with IVIM and DCE-MRI.

Study description

Background summary

Pancreatic ductal adenocarcinoma (PDAC) is the fourth leading cause of cancer death worldwide and despite many efforts has retained a very grim overall 5-year survival of 5%. When surgery with curative intent is possible, 5-year survival increases up to circa 10-20%, but at the time of diagnosis this is only feasible in 20% of patients. Patients with Locally Advanced (i.e. non-metastatic, but irresectable) Pancreatic Cancer (LAPC) show increased progression-free and overall survival after combination chemotherapy such as

5-fluorouracil, leucovorin, irinotecan and oxaliplatin (FOLFIRINOX), with 20% even becoming eligible for surgery with curative intent. Stromal deposition is an important component of PDAC and its amount is related to therapy resistance. Therefore, the amount of stroma could potentially be used as a biomarker for the efficacy of the treatment. We hypothesize that Magnetic Resonance Elastography (MRE) can be used to predict the cytotoxic treatment efficacy. This new imaging technology provides architectural information on PDAC composition.

Study objective

Predict response to FOLFIRINOX treatment in patients with LAPC based on baseline stiffness values derived with MRE.

Study design

This prospective observational study is aimed to determine if MRE can be used as an imaging biomarker to predict the response to FOLFIRINOX in patients with LAPC. In this study, a total of 50 adult patients with LAPC who will be treated with FOLFIRINOX will be scheduled for an MRI scan session which will include an MRE, DWI and DCE-MRI scan. The MRI scan will take place in the Amsterdam UMC.

Study burden and risks

Participation in this study does not lead to immediate advantage for the participant. The overall aim of the ASAP study is to gain further insight in treatment efficacy of FOLFIRINOX in patients with LAPC using MRE, DWI and DCE-MRI.

The burden for the patients will consist of a 1 x 45 minutes MRI scan session including MRE, DWI and DCE-MRI.

During the MRE scan, an external vibration is applied to the body that is not harmful or painful for the patient. MRI is a safe imaging procedure that does not use ionizing radiation and has low inherent risks. The subject is asked to fast for at least 4 hours prior to the scan. Patients with MRI contraindications are excluded from participation in this study.

For DCE-MRI, MR contrast agent Dotarem (gadoteric acid) will be used. This product is used daily at the Department of Radiology and Nuclear Medicine of the Amsterdam UMC. Side-effects of Dotarem administration are rarely observed. The most common side effects include a short sensation of warmth or very mild pain in the arm and a strange oral taste, this does not constitute an allergic reaction. Indeed, allergic reactions are rare (<0.1% of patients). Medications to treat contrast-induced hypersensitivity reactions are readily available at our site. In case of known renal insufficiency (eGFR <30 ml/min/1.73m2),

subjects cannot participate.

In summary, given that MRI, MR Elastography and MR contrast administration are safe with the correct application of our exclusion criteria (which includes MRI and contrast-agent contra-indications), the risk in participating in this study is considered negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

18 years or older
Written informed consent
Scheduled for treatment with FOLFIRINOX
LAPC defined according to the Dutch Pancreatic Cancer Group Criteria

Exclusion criteria

General MRI contraindications
History of allergic reaction to Gadolinium-containing compounds
Known renal failure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-08-2022
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	29-07-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660

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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	NL76400.018.21