Accuracy of MRI versus CT iMAGing to assess resectability following FOLFIRINOX for locally advancEd pancreatic cancer (IMAGE)

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The primary objective of this study is to investigate the capability of diffusion weighted magnetic resonance imaging (DWI) to assess tumor resectability after FOLFIRINOX, compared to standard CT scan.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON43456

Source
ToetsingOnline

Brief title
IMAGE

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
pancreatic cancer, pancreatic carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: KWF

Intervention

Keyword: cancer, imaging, pancreas, resectability

Outcome measures

Primary outcome

Primary outcome measure: correct assessment of tumor resectability according to

DWI MRI, compared to standard CT.

Secondary outcome

Active tumor size on MRI and CT will be compared, and in patients receiving

resection also compared to the active tumor size in the resected pathology

specimen.

Study description

Background summary

Pancreatic cancer is the fifth leading cause of cancer-related death in the Netherlands. Approximately 40% of patients present with locally advanced, i.e. unresectable, pancreatic cancer (LAPC). Standard chemotherapy in these patients offers only a limited survival benefit. With the improved FOLFIRINOX chemotherapy, various studies, including from our own center (the IMPALA study, NL44713.018.13), demonstrate that in a substantial proportion of patients (10-20%) the tumor is downstaged to such an extent that it becomes eligible for resection. Unfortunately, current standard computed tomography (CT) imaging is extremely inaccurate to determine resectability following FOLFIRINOX (specificity 0-50%). With better imaging, patients could be better stratified for curative or palliative treatment options.

Study objective

The primary objective of this study is to investigate the capability of diffusion weighted magnetic resonance imaging (DWI) to assess tumor resectability after FOLFIRINOX, compared to standard CT scan.

Study design

Monocenter cohort study

Intervention

MRI scan with diffusion weighted imaging (DWI)

Study burden and risks

the risks associated with administration of contrast fluid and placement of an intravenous line are minimal

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with locally advanced pancreatic cancer, without distant metastases, after 2 months of FOLFIRINOX chemotherapy undergoing explorative laparotomy

Exclusion criteria

Contra-indications for MRI

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-09-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL56565.018.16