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

Published: 14-03-2016 Last updated: 17-04-2024

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

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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

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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

NI

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