Irreversible electroporation treatment in patients with pancreatic locally advanced adenocarcinoma

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The objective of this study is to investigate the amount of clinically relevant complications (defined by Clavien-Dindo score 3 or higher) caused by IRE in patients with locally advanced, non-resectable, non-metastasized, pancreatic cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON40224

Source
ToetsingOnline

Brief title
IMPALA

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified
- Gastrointestinal therapeutic procedures

Synonym
Pancreatic adenocarcinoma, Pancreatic Cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: ablation, irreversible electroporation, pancreatic cancer, treatment

Outcome measures

Primary outcome

Primary endpoint: Clavien-Dindo score 3 or higher complications, these are defined as complications leading to re-intervention (endoscopic, surgical or radiological), admission to the intensive care unit, or mortality.

Secondary outcome

Secondary endpoints: success rate of completing the procedure, duration of the procedure, intraprocedural complications, time to functional recovery, length of hospital stay, complications, readmissions, ablation effect as recorded on cross-sectional imaging, and survival (2 year survival, median survival, progression free survival).

Study description

Background summary

Pancreatic adenocarcinoma is a devastating disease with a 2-year overall survival below 10%. Although surgical resection offers the only chance for cure, 80% of patients present with unresectable disease because of local progression or metastases. The treatment for these patients is palliative chemotherapy, radiotherapy, or both, but offers only marginal survival advantage. Recently, irreversible electroporation (IRE), a non-thermal ablation technique, has been suggested as a novel treatment for the 40% of patients with locally advanced pancreatic cancer, without metastases. Some clinical data suggest that IRE, when performed during surgical exploration, may improve overall survival with 9 months with limited risks of complications.

Study objective

The objective of this study is to investigate the amount of clinically relevant complications (defined by Clavien-Dindo score 3 or higher) caused by IRE in patients with locally advanced, non-resectable, non-metastasized, pancreatic cancer.

Study design

A phase II safety study

Intervention

IRE during open surgery (during the same procedure as intended for resection or confirmation of unresectability).

Study burden and risks

Based on current literature (one prospective study, n=54) the estimated gain in overall survival is 9 months (from 11 to 20 months). According to the current literature clinically relevant complications are expected in up to 17% of procedures with 1-2% mortality.

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

- Age 18 years or older
- Capable of providing written and oral informed consent
- Physically fit to undergo explorative laparotomy
- Pancreatic cancer confirmed with pathology (either pre- or intraoperative, pathological diagnosis must be either pancreatic adenocarcinoma or non-intestinal cholangiocarcinoma located in the pancreas) and non resectability because of locally advanced growth (stage III) during surgical exploration
- One of the following:
* Potentially resectable panreatic cancer based on imaging and planned for surgical exploration with intend for resection, this includes 2 groups of patients
* Patients with resectable disease at primary evaluation but are considered non-resectable during surgical exploration
$ Patients with initially non-resectable disease because of locally advanced pancreatic cancer without metastases, who have stable or regressive (non-metastasized) disease after 3 months of chemotherapy
* Locally advanced pancreatic cancer based on imaging without options for non-operative drainage of stomach and bileducts and therefore planned for surgical exploration with intend for bypass surgery

Exclusion criteria

- Resectable pancreatic cancer during explorative laparotomy
- Presence of metastatic disease (peritoneal, liver or other)
- Pathological diagnosis of intestinal-type cholangiocarcinoma
- History of cardiac arrhythmia*s
* Sinus tachycardia (BPM>100)
* Sick sinus syndrome
* Sinoatrial exit block
* AV block
* Sinus node reentry
* Presence of a pacemaker or defibrillator
- Recent history of myocardial infarction
- History of epilepsy
- Partial portal vein thrombosis
- Both narrowing (sclerosis) of the portal vein and a reduced diameter of either the common

hepatic artery, celiac trunc or superior mesenteric artery of >50%

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2013
Enrollment:	106
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-01-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	15-08-2014
Application type:	Amendment
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	NL44713.018.13

Study results

Date completed:	07-08-2015
Actual enrolment:	50