Behandeling met het Nanoknife® systeem bij patiënten met alvleesklierkanker die niet operatief verwijderd kan worden.

Gepubliceerd: 31-10-2013 Laatst bijgewerkt: 13-12-2022

Our primary hypothesis is that IRE will add a maximum of 28% clinically relevant complications, defined as Clavien-Dindo score 3 or higher, to the current 28% of complications associated with palliative treatment.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20237

Bron
NTR

Verkorte titel
IMPALA

Aandoening

pancreatic cancer, pancreatic adenocarcinoma, local ablative therapy, irreversible electroporation

alvleesklierkanker, pancreascarcinoom, lokale ablatietherapie, irreversibele electroporatie

Ondersteuning

Primaire sponsor: AMC Amsterdam
Overige ondersteuning: AMC Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome is the effect of IRE on severe morbidity and mortality occurring until 90 days after IRE treatment. Severe morbidity is defined as defined as Clavien-Dindo score 3 or more.

Toelichting onderzoek

Achtergrond van het onderzoek

Subjects will be recruited in the Netherlands

Doel van het onderzoek

Our primary hypothesis is that IRE will add a maximum of 28% clinically relevant complications, defined as Clavien-Dindo score 3 or higher, to the current 28% of complications associated with palliative treatment.

Onderzoeksopzet

After discharge patients will be seen in the outpatient clinic as is routine practice for postoperative patients (after 6 weeks, after 3, 6, 9, 12 and 24 months) for clinical evaluation and laboratory testing of tumor markers (CEA, CA 19.9). A CT scan will be performed after 12 weeks and in case of complaints such as pain and/or weight loss that raise suspicion of disease progression. The date of disease progression is defined as the day that symptoms began, which on the CT are later documented to be related to disease progression.

Onderzoeksproduct en/of interventie

Patients who are deemed eligible for the procedure undergo the same work-up, treatment and follow-up as is currently the case for patients with potential resectable pancreatic cancer and patients undergoing bypass surgery for locally advanced pancreatic cancer in the Netherlands. This includes baseline laboratory testing, computed tomography scan and anesthesia evaluation.

A biliary metal stent is a contra-indication for IRE due to possible interference of the electroporation with the metal in the stent. This is not likely to pose a relevant problem as approximately 90% of patients in the AMC Amsterdam do not present with a metal biliary stent in the experience of the study group. Patients will either have a plastic stent or no

stent. In case a patient presents with a metal stent, and the patient is eligible for this study, the stent can be removed during explorative surgery. After surgery, no stent is required as generally in those circumstances a biliary bypass will be created.

The IRE procedure will be performed under general anesthesia with complete muscle paralysis in the operation room. After confirmation of unresectability because of LAPC (stage III pancreatic cancer), IRE will be performed by a trained interventional radiologist during explorative laparotomy (the same procedure).

The Nanoknife® IRE device (AngioDynamics, Amsterdam Zuid-Oost) is used in this study. The IRE is set up to produce 70-microsecond high-voltage (1500-3000 V) direct current (25-45 A) electrical pulses. Typically, 90 pulses will be delivered in 9 sets of 10 pulses between paired unipolar electrodes. The spacing between electrodes can be maximal 2.0 cm. The voltage setting for each electroporation will be determined by the distance between each pair of electrodes, with the intent to generate at least 1000 V between electrodes. Electrodes will be placed under visual and ultrasound guidance. The generator will be programmed to stop delivery and recharge if the current flow exceeds 50 A. Pull back will be performed if the target treatment zone is greater than 2 cm, and treatment will be repeated to cover the entire target. The number of probes used for ablation is depending on tumor size. (For a relatively 2-dimensional ablation zone with a size of less than 30x25x10 mm, two probes will be used (one active and one standard probe). When the shape of the ablation zone is more 3-dimensional, with a size of maximum 30x25x20,5 mm, three probes will be used (one active and two standard). For an ablation of a larger zone, maximum size of 30x25x25 mm four probes will be used. Five probes will be used for tumors up to 30x40x30 mm and for larger tumors up to 30x47x32 six probes will be used.)

All pulses will be administered in the absolute refractory period with use of electrocardiographic (ECG) synchronization to avoid triggering ventricular arrhythmia.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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) confirmed during surgical exploration

• One of the following:

o Potentially resectable pancreatic 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

o Locally advanced pancreatic cancer based on imaging without options for non-operative drainage of stomach and bile ducts and therefore planned for surgical exploration with intend for bypass surgery

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

o Sinus tachycardia (BPM>100)

o Sick sinus syndrome

o Sinoatrial exit block

o AV block

o Sinus node reentry

o Presence of a pacemaker or defibrillator

• Recent history of myocardial infarction

• History of epilepsy

• Partial portal vein thrombosis

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2013
Aantal proefpersonen:	106
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	31-10-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4079
NTR-old	NTR4230
Ander register	NL44713.018.13 : METC
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A