CROSSFIRE Trial: Comparing the Efficacy of Irreversible Electroporation With Radiotherapy

Gepubliceerd: 27-05-2016 Laatst bijgewerkt: 15-05-2024

For patients diagnosed with non-metastatic locally advanced pancreatic cancer, a combination of chemotherapy (FOLFIRINOX) plus local tumor destruction using stereotactic ablative radiotherapy (SABR) or irreversible electroporation (IRE), will result...

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

Samenvatting

ID

NL-OMON22388

Bron
Nationaal Trial Register

Verkorte titel
CROSSFIRE trial

Aandoening

Pancreatic cancer

Ondersteuning

Primaire sponsor: VU University Medical Center, Amsterdam
Overige ondersteuning: Adessium Foundation
VU University Medical Center
Angiodynamics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome of the study is efficacy in terms of overall survival.

Toelichting onderzoek

Achtergrond van het onderzoek

Pancreatic cancer has the highest mortality rate of all major cancers; 94% of pancreatic cancer patients will die within five years of diagnosis, 74% within the first year of diagnosis; only 6% will survive for more than five years. Surgical resection is the only curative option. However, about 40% present with non-metastatic locally advanced pancreatic carcinoma (LAPC; AJCC stage III). These patients are not eligible for surgical resection because the tumor involves major blood vessels such as the superior mesenteric artery, celiac axis, common hepatic artery and/or portal vein. These patients are currently treated with palliative chemotherapy as first line therapy. Focal therapy using external beam radiation therapy (EBRT) may further improve survival, but outcome remains poor. Stereotactic ablative radiotherapy (SABR) is a form of EBRT that has important advantages over conventional radiotherapy such as a more precise and greater biological dose delivery and hence less toxicity and presumably better outcome.

For patients diagnosed with LAPC, a combination of chemotherapy plus local tumor destruction using irreversible electroporation (IRE), a novel tumor ablation technique, has recently shown great promise. IRE is based on permeabilization of the cell membrane through electrical pulses leading to apoptosis. Theoretically, IRE only affects viable tumor tissue, leaving surrounding vital structures relatively intact. It is therefore considered to cause less morbidity than thermal ablative strategies.

The CROSSFIRE-trial is a prospective, randomized controlled phase-II/III trial.The primary aim of this study is to compare the efficacy of chemotherapy and IRE (experimental arm) to the efficacy of chemotherapy and radiation (control arm) in patients with locally advanced, non-resectable, non-metastasized, pancreatic cancer.

In total, 138 patients with histologically proven locally advanced pancreatic adenocarcinoma (AJCC stage III), aged ≥ 18 years will be included. Patients with a specific cardiac history (arrhythmias, pacemaker), pre-existent ECG-abnormalities and/or non-retrievable metallic self-expanding biliary stents are excluded from participation. Patients will be randomly allocated to receive either chemotherapy and radiation (control arm) or chemotherapy and IRE (experimental arm).

Doel van het onderzoek

For patients diagnosed with non-metastatic locally advanced pancreatic cancer, a combination of chemotherapy (FOLFIRINOX) plus local tumor destruction using stereotactic ablative radiotherapy (SABR) or irreversible electroporation (IRE), will result in a prolonged overall survival.

Onderzoeksopzet

The follow-up period will be till the date of death from any cause.

Onderzoeksproduct en/of interventie

IRE is based on permeabilization of the cell membrane through electrical pulses leading to apoptosis. Theoretically, IRE only affects viable tumor tissue, leaving surrounding vital structures relatively intact. It is therefore considered to cause less morbidity than thermal ablative strategies.

Stereotactic ablative radiotherapy (SABR) is a form of external beam radiation that has important advantages over conventional radiotherapy such as a more precise and greater biological dose delivery and hence less toxicity and presumably better outcome.

Contactpersonen

Publiek

L.G.P.H. Vroomen
Amsterdam
The Netherlands

Wetenschappelijk

L.G.P.H. Vroomen
Amsterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

Inclusion Criteria:

- Radiologic confirmation of LAPC by at least ceCT of chest and abdomen (with the upper abdomen scanned according to a dedicated 3mm slice multiphase pancreatic tumor protocol);

- Maximum tumor diameter ≤ 5 cm;

- Histological or cytological confirmation of pancreatic adenocarcinoma;

- Age > 18 years;

- ASA-classification 0 – 3; World Health Organisation scale (WHO) performance status 0 – 1 ;

- Adequate bile drainage in case of biliary obstruction;

- Written informed consent;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion Criteria:

- Resectable pancreatic adenocarcinoma as discussed by our multidisciplinary hepatobiliary team;

- The presence of suspect lymph nodes

- Stage IV pancreatic carcinoma;

- Trans-mucosal tumor invasion into surrounding duodenum or stomach;

- History of epilepsy;

- History of cardiac disease:

o Congestive heart failure >NYHA class 2;

o Active Coronary Artery Disease (defined as myocardial infarction within 6 months prior to screening);

o Ventricular cardiac arrhythmias requiring anti-arrhythmic therapy or pacemaker (beta

blockers for antihypertensive regimen are permitted; atrial fibrillation is not contra-indicated);

- Uncontrolled hypertension. Blood pressure must be ≤160/95 mmHg at the time of screening on a stable antihypertensive regimen;

- Compromised liver function (e.g. signs of portal hypertension, INR > 1,5 without use of anticoagulants, ascites);

- Uncontrolled infections (> grade 2 NCI-CTC version 3.0);

- Pregnant or breast-feeding subjects. Women of childbearing potential must have a negative pregnancy test performed within 7 days of the start of treatment;

- Immunotherapy prior to the procedure;

- Radiotherapy prior to study enrollment;

- Previous surgical therapy for pancreatic cancer;

- Second primary malignancy, except adequately treated non-melanoma skin cancer, in situ carcinoma of the cervis uteri or other malignancies treated at least 5 years previously without signs of recurrence;

- Allergic to contrast agent.

- Any implanted stimulation device;

- Any condition that is unstable or that could jeopardize the safety of the subject and their compliance in the study;

- Non-removable Self Expanding Metal biliary Stent (SEMS), which cannot be removed during surgery.

- Contra-indications for MRI since no safety data for 0.35 Tesla MRI scanners are available on electronic devices such as pacemakers or implanted defibrillators, deep brain stimulators, cochlear implants, this constitutes an absolute contraindication for this study, even for devices that have been considered safe for MRI scans with higher field strengths.

o Patients who have a metallic foreign body in their eye, or who have an aneurysm clip in their brain, cannot have an MRI scan since the magnetic field may dislodge the metal

o Patients with severe claustrophobia may not be able to tolerate an MRI scan

o Patients with a hip prosthesis will not be eligible for the MRI scan

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-04-2016
Aantal proefpersonen:	138
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-05-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50215
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5722
NTR-old	NTR5875
CCMO	NL55158.029.15
OMON	NL-OMON50215

Resultaten