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

Gepubliceerd: 16-05-2018 Laatst bijgewerkt: 15-05-2024

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

Samenvatting

ID

NL-OMON29184

Bron
NTR

Verkorte titel
ANTILOPE

Aandoening

Pancreatic cancer; locally advanced pancreatic cancer; LAPC

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Dutch Cancer Society (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint is treatment time of CT-guided IRE.

Toelichting onderzoek

Achtergrond van het onderzoek

Pancreatic ductal adenocarcinoma (i.e. pancreatic cancer) is one of the leading causes of cancer-related deaths worldwide. For the 40% of patients who present with non-metastatic locally
advanced (unresectable) disease, CT-guided percutaneous irreversible electroporation (IRE) has provided promising results but confirmation from randomized controlled trials (RCTs) are lacking. Before largescale RCTs can be designed, data from smaller, randomized feasibility studies are required to determine which of the IRE protocols should be used. The aim of this study is therefore to compare the two most frequently used clinical IRE protocols including state-of-the-art chemotherapy in locally advanced pancreatic cancer (LAPC).

Onderzoeksopzet

March 2018 start inclusinon, expected duration 2-2.5 years. Expected last inclusion: September 2020.

Onderzoeksproduct en/of interventie

Eligible patients will be randomized for IRE either with the Fixed Amperage or the Targeted Amperage protocol. IRE will be performed under general anaesthesia with full muscle relaxation. Chemotherapy, follow-up including imaging will all be performed according to standard care.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥18 years

- LAPC (either primary or tumour recurrence following resection), defined by the DPCG consensus criteria as: arterial involvement >90□ or venous involvement >270)

- At least RECIST stable disease after at least 2 months of chemotherapy according to current clinical practice

- Capable of providing written and oral informed consent

- Candidate for IRE, maximum diameter of the tumour 5cm

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Participation in the PELICAN trial focussing on radiofrequency ablation for LAPC*

- Eligibility for resection

- Bleeding disorders which cannot be corrected with medication

- Inability/unwillingness to interrupt anticoagulation therapy

- ASA 3/4

- ICD/pacemaker incompatible with IRE

- Both partial stenosis of the portal vein and hepatic artery of >50%

- Pregnancy

- Metastatic pancreatic cancer

- Presence of a uncovered metal biliary stent in the IRE field

- Tumour with a maximum diameter >5cm

- Epilepsy episodes in the past 6 months

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	08-03-2018
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-05-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55702
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7015
NTR-old	NTR7213
CCMO	NL59644.018.17
OMON	NL-OMON55702

Resultaten