

Short-term palliative radiation for painful irresectable pancreatic cancer (PainPanc): a prospective phase 2 study

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Painreduction for 67% of patients with a locally advanced or local recurrent pancreatic carcinoma through a short radiotherapy scheme (single arm phase 2 study)

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20425

Bron

NTR

Verkorte titel

PAINPANC

Aandoening

Painful Locally advanced or locally recurrent pancreatic cancer

Ondersteuning

Primaire sponsor: Academic Medical Center

Meibergdreef 9

1105 AZ Amsterdam, the Netherlands

Overige ondersteuning: No funding was requested for this research.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate whether pain relief is successful 4 weeks after the last radiation (7 weeks after start of treatment) . A short course of radiation (3 x 8 Gy) will be given in patients with painful irresectable pancreatic cancer, primary or recurrent.

Toelichting onderzoek

Achtergrond van het onderzoek

Pancreatic cancer has an extremely poor prognosis. It is the fifth leading cause of cancer death in the Netherlands with an overall 2-year survival of less than 10%. This has hardly improved over the last two decades. Less than 15% of all patients present with resectable disease. The majority of patients have locally advanced and/or metastasized disease and are treated with palliative intent.

Pain is an important symptom in pancreatic cancer and leads to a strong reduction in quality of life. At time of diagnosis, 30-40% of the patients report pain as a dominant symptom which rises to 90% shortly before death. Inadequate pain control may lead to a situation where pain becomes disabling and requires hospitalization for pain management. Therefore successful pain management is often viewed as the key management for a better quality of life. Pain management options range from pharmacologic treatment to invasive treatment such as nerve blockades. Radiation has also shown to give pain reduction, even though not much research has been done. With this study we would like to research and document the pain relief of shortcourse radiation and the effect of quality of life.

Doel van het onderzoek

Painreduction for 67% of patients with a locally advanced or local recurrent pancreatic carcinoma through a short radiotherapy scheme
(single arm phase 2 study)

Onderzoeksopzet

baseline, after each fraction, and at 4, 5, 7, 11, en 19 weeks after start of radiation and once per 3 months thereafter

Onderzoeksproduct en/of interventie

radiotherapy 3 X 8 Gy, once per week.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Pain with a NRS $\geq$ 2 as a result of pancreatic cancer, not sufficiently responding to oral, transdermal pain medication or celiac plexus blockade.
2. Primarily irresectable or locally recurrent pancreatic cancer with or without metastases
3. Preferably histological or cytological confirmed adenocarcinoma of the pancreas
4. WHO performance status $\leq$ 2
5. Diagnostic CT-scan not older than 3 months before study entry
6. Age $\geq$ 18 years
7. If the patient is or was treated with chemotherapy, time interval between the course of chemotherapy and start of radiation should at least be 14 days.
8. Written informed consent

9. The ability to answer and fill out the questionnaires

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Resectable or borderline resectable tumors without distant metastases
2. Endocrine pancreatic cancer or suspicion of metastasis in the pancreas
3. Pregnant woman

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2015
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

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	NL4896
NTR-old	NTR5143
Ander register	:

Resultaten

Samenvatting resultaten

van Geenen RC, Keyzer-Dekker CM, van Tienhoven G, Obertop H, Gouma DJ. Pain management of patients with unresectable peripancreatic carcinoma. World J Surg. 2002;26:715-20

Ceha HM, van Tienhoven G, Gouma DJ, Veenhof CH, Schneider CJ, Rauws EA, et al. Feasibility and efficacy of high dose conformal radiation for patients with locally advanced pancreatic carcinoma. Cancer. 2000;89:2222-9

Morganti AG, Trodella L, Valentini V, Barbi S, Macchia G, Mantini G, et al. Pain relief with short-term irradiation in locally advanced carcinoma of the pancreas. J Palliat Care. 2003;19:258-62