Efficacy and Feasibility of Combining FOLFIRINOX and Stereotactic Radiotherapy for Patients With Irresectable Locally Advanced Pancreatic Cancer.

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Combining FOLFIRINOX chemotherapy and stereotactic radiotherapy can lead to better regional tumor control and better overall survival in patients with locally advanced pancreatic cancer.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27030

Bron
Nationaal Trial Register

Verkorte titel
LAPC-1

Aandoening

locally advanced pancreatic cancer
pancreatic neoplasm
FOLFIRINOX
stereotactic radiotherapy

Ondersteuning

Primaire sponsor: Foundation for Liver and Gastrointestinal Research
Overige ondersteuning: Foundation for Liver and Gastrointestinal Research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- overall survival

Toelichting onderzoek

Doel van het onderzoek

Combining FOLFIRINOX chemotherapy and stereotactic radiotherapy can lead to better regional tumor control and better overall survival in patients with locally advanced pancreatic cancer.

Onderzoeksopzet

- Pre-treatment evaluation (pre-screening)

- screening

- Initial visit to the outpatient clinic (baseline)

- FOLFIRINOX treatment period, consisting of the following visits:

Cycle 1 (week 2)

Cycle 2 (week 4)

Cycle 3 (week 6)

Cycle 4 (week 8)

CT Evaluation (week 9)

Cycle 5 (week 10)

Cycle 6 (week 12)

Cycle 7 (week 14)

Cycle 8 (week 16)

CT evaluation (week 17)

- Stereotactic radiation pre-treatment visit (only for non-metastatic patients) (week 18)

- Stereotactic radiation treatment period (dosing days 1,2,3,4 and 5, week 20)

- Follow up period consisting of the following visits:
FU visit 1: 6 weeks after RT (week 26)

FU visit 2: 3 months after RT (week 32)

FU visit 3: 6 months after RT (week 46)

FU visit 4: 9 months after RT (week 58)

FU visit 5: 12 months after RT (week 70)

FU visit 6: 15 months after RT (week 82)

FU visit 7: 18 months after RT (week 94)

FU visit 8: 21 months after RT (week 106)

FU visit 9: 24 months after RT (week 118)

Onderzoeksproduct en/of interventie

stereotactic radiotherapy

Contactpersonen

Publiek

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van Eijck

Wetenschappelijk

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van Eijck

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Cytological or histologically confirmation of pancreatic cancer.

- WHO performance status of 0 or 1

- ASA classification I or II

- Tumor considered locally advanced after diagnostic work-up including CT-imaging and diagnostic laparoscopy.

- No evidence of metastatic disease

- Largest tumor diameter < 7 cm x 7 cm x 7 cm

- Normal renal function (Creatinine ≥ 30 ml/min).

- Normal liver tests (bilirubin < 1.5 times normal; ALAT/ASAT < 5 times normal)

- Normal bone marrow function (WBC > 3.0 x 10e9/L, platelets > 100 x 10e9/L and hemoglobin > 5.6 mmol/l)

- Age > 18 years and < 75 years

- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Prior radiotherapy, chemotherapy or resection (bypass surgery allowed).

- Lymph node metastases from primary tumor outside the field of radiation.

- Second primary malignancy except in situ carcinoma of the cervix, adequately treated non-melanoma skin cancer, or other malignancy treated at least 3 years previously without evidence of recurrence.

- Pregnancy, breast feeding.

- Serious concomitant systemic disorders that would compromise the safety of the patient or his/her ability to complete the study, at the discretion of the investigator.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-12-2014
Aantal proefpersonen:	51
Type:	Onbekend

Ethische beoordeling

Positief advies

Datum:	09-03-2015
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	NL4812
NTR-old	NTR5084
Ander register	NCT02292745 : ClinicalTrials.gov

Resultaten