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

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27030

Source
NTR

Brief title
LAPC-1

Health condition

locally advanced pancreatic cancer
pancreatic neoplasm
FOLFIRINOX
stereotactic radiotherapy

Sponsors and support

Primary sponsor: Foundation for Liver and Gastrointestinal Research
Source(s) of monetary or material Support: Foundation for Liver and Gastrointestinal Research

Intervention

Outcome measures

Primary outcome

- overall survival

Secondary outcome

- number of toxicity events related to chemotherapy

- radiological response after chemotherapy and radiotherapy

- number of resections at end of stereotactic radiotherapy

- time to locoregional disease progression

- time to development of distant metastases

- predictive value of a set of biological markers for treatment response (miRNAs)

Study description

Study objective

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

Study design

- 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)

Intervention

stereotactic radiotherapy

Contacts

Public
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Scientific
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van Eijck

Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-12-2014
Enrollment:	51
Type:	Unknown

Ethics review

Positive opinion

Date:	09-03-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4812
NTR-old	NTR5084
Other	NCT02292745 : ClinicalTrials.gov

Study results