

Gemcitabine en radiotherapie in combinatie met panitumumab bij patiënten met niet uitgezaaide, inoperabele alvleesklierkanker.

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The addition of panitumumab to radiotherapy plus gemcitabine will increase the number of patients who are alive and progression free at 7 months.

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

Samenvatting

ID

NL-OMON25995

Bron

NTR

Verkorte titel

Vectibix 20080686

Aandoening

Pancreatic cancer
Pancreas cancer
Alvleesklierkanker
Pancreaskanker

Ondersteuning

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Overige ondersteuning: AMGEN B.V.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Phase I part:

To determine the recommended safe dosing for the combination of chemoradiation with gemcitabine plus panitumumab in patients with inoperable locally advanced pancreatic cancer.

Phase II part:

1. To investigate the proportion of patients with inoperable locally advanced pancreatic cancer receiving chemoradiation with gemcitabine plus panitumumab as first line treatment, that is progression-free at 7 months;

2. To evaluate the safety and tolerability for the combination of chemoradiation with gemcitabine plus panitumumab in patients with inoperable locally advanced pancreatic cancer.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a phase I/II, multi-center dose escalation study.

Phase I:

Patients will be enrolled in cohorts of 3 per dose level until the MTD of panitumumab has been established.

Phase II:

Up to approximately 56 patients will be treated at the MTD level of panitumumab as established in the phase I part of the study.

Based on the historic data of patients with pancreatic cancer treated with gemcitabine based chemoradiation, we aim to increase the number of patients who are alive and progression free at 7 months from the historical value of 50% to 70% with the combination treatment of chemoradiation plus panitumumab.

Doel van het onderzoek

The addition of panitumumab to radiotherapy plus gemcitabine will increase the number of patients who are alive and progression free at 7 months.

Onderzoeksopzet

During the first 6 weeks panitumumab will be administered weekly in combination with radiotherapy plus gemcitabine. From week 8 and further gemcitabine will be administered as monotherapy until disease progression or unacceptable toxicity.

Onderzoeksproduct en/of interventie

Addition of panitumumab to radiotherapy plus gemcitabine.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Histological or cytological confirmed pancreatic cancer;
2. Not eligible for curative resection;
3. No distant metastases present;
4. Previously untreated with chemotherapy and anti-cancer biologicals for current malignancy;
5. No other current malignant disease, except for basal cell carcinoma of the skin;
6. Measurable or evaluable disease as defined by RECIST 1.1 criteria;
7. Performance status 0-2 Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) Scale;
8. Age ≥ 18 years;
9. Adequate haematological and biological functions:
 - A. Bone marrow function:
 - i. Neutrophils $\geq 1.5 \times 10^9/L$;
 - ii. Platelets $\geq 100 \times 10^9/L$;
 - iii. Hb ≥ 6 mmol/L.
 - B. Hepatic function:
 - i. AST/ALT and alkaline phosphatase (ALP) $\leq 2.5 \times$ institutional upper limit of normal (ULN);
 - ii. Bilirubin ≤ 1.5 times institutional ULN.
 - C. Renal function:
 - i. eGFR >50 ml/min.
 - D. Metabolic Function:
 - i. Magnesium $\geq$ lower limit of normal;
 - ii. Calcium $\geq$ lower limit of normal.

10. No imminent bowel obstruction;
11. No active bleeding;
12. No uncontrolled infection;
13. Patients with reproductive potential must use effective contraception. Female patients must have a negative pregnancy test;
14. Signed informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Participation in another therapeutic clinical study within 30 days of enrollment or during this clinical study;
2. No adequate radiation therapy possible: based on the opinion of the radiation oncologist when radiation therapy cannot be performed because radiation field is too large (PTV volume too large or OAR too high);
3. History of allergic reactions to gemcitabine or antibody treatment;
4. Presence of any serious concomitant systemic disorders incompatible with the clinical study (e.g. uncontrolled inter-current illness including ongoing or active infection, uncontrolled hypertension);
5. Clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) within 1 year before enrolment/randomization;
6. History of interstitial lung disease e.g. pneumonitis or pulmonary fibrosis or evidence of interstitial lung disease on baseline chest CT scan;
7. Presence of any significant central nervous system or psychiatric disorder(s) that would hamper the patient's compliance;
8. Pregnant or breastfeeding women;
9. Absence of adequate contraception for both male and female fertile patients for the duration of the study; and also for six months after last treatment;
10. Known positive status for HIV and/or hepatitis B or C;
11. Any reason why, in the investigator's opinion, the patient should not participate in the

study;

12. Drug or alcohol abuse.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	14-07-2010
Aantal proefpersonen:	63
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	02-08-2010
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	NL2335
NTR-old	NTR2441
Ander register	METC VUmc : 2010/45
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A