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

No registrations found.

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

Summary

ID

NL-OMON25995

Source
NTR

Brief title
Vectibix 20080686

Health condition

Pancreatic cancer
Pancreas cancer
Alvleesklierkanker
Pancreaskanker

Sponsors and support

Primary sponsor: Prof. dr. H.M.W. Verheul, M.D., Ph.D.
Head Department of Medical Oncology
VU University Medical Center
De Boelelaan 1117
1081 HV Amsterdam
Phone: +31-20-4444321/300
Fax: + 31-20-4444079
Email: h.verheul@vumc.nl

Source(s) of monetary or material Support: AMGEN B.V.

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. To assess early signs of clinical activity of the combination of chemoradiation with gemcitabine plus panitumumab in patients with inoperable locally advanced pancreatic cancer;

2. To assess the clinical response rate of the combination of chemoradiation with gemcitabine plus panitumumab in patients with inoperable locally advanced pancreatic cancer;

3. To assess time-to-progression (TTP) and overall survival amongst patients with inoperable locally advanced pancreatic cancer receiving chemoradiation with gemcitabine plus panitumumab as first line treatment.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

Addition of panitumumab to radiotherapy plus gemcitabine.

Contacts

Public
De Boelelaan 1117
H.M.W. Verheul
Amsterdam 1081 HV

The Netherlands
+31 (0)20 4444321/300
Scientific
De Boelelaan 1117
H.M.W. Verheul
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4444321/300

Eligibility criteria

Inclusion criteria

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 ≥ 1.5 x 109/L;

ii. Platelets ≥ 100 x 109/L;

iii. Hb ≥ 6 mmol/L.

B. Hepatic function:

i. AST/ALT and alkaline phosphatase (ALP) ≤ 2.5 x institutional upper limit of normal (ULN);

ii. Bilirubin ≤ 1.5 times institutional ULN.

C. Renal function:

i. eGFR >50ml/min.

D. Metabolic Function:

i. Magnesium ≥ lower limit of normal;

ii. Calcium ≥ 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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-07-2010
Enrollment:	63
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-08-2010
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	NL2335
NTR-old	NTR2441
Other	METC VUmc : 2010/45
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A