NABGEM study: nab-paclitaxel plus gemcitabine in patients with locally unresectable pancreatic cancer.

Gepubliceerd: 24-08-2017 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON23547

Bron
NTR

Verkorte titel
NABGEM study

Aandoening

Locally advanced pancreatic cancer, pancreatic cancer, pancreascarcinoom, lokaal irresectabel pancreascarcinoom

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam
Overige ondersteuning: Investigator initiated trial
Financial support of Celgene

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

disease controle rate

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Nab-paclitaxel plus gemcitabine has shown its superiority compared to gemcitabine monotherapy in patients with metastatic pancreatic cancer with a median overall survival of 8.7 months versus 6.6 months. The regimen might also benefit patients with locally advanced pancreatic cancer (LAPC) but prospective data are lacking.

Objective: To investigate disease control after nab-paclitaxel plus gemcitabine in patients with locally advanced pancreatic cancer.

Study design: Prospective cohort study.

Study population: Patients with histological or cytological proven LAPC according to the Dutch Pancreatic Cancer Group definition.

Intervention: Nab-paclitaxel plus gemcitabine chemotherapy.

Primary endpoint: Disease control (non-progressive disease according to RECIST 1.1 criteria) after 2 cycles, confirmed after 4 cycles.

Secondary endpoint: Toxicity, progression-free survival, overall survival, tumor marker response, resection rate and quality of life.

Expected outcome: A disease control of 60% is expected and will be clinically relevant with a lower reference bound of 45%.

Statistics: A sample size of 136 patients was calculated. Descriptive statistics will be used to define the count of patients who achieved disease control. Binomial test will be used to test whether the probability of a disease control rate is different from 45%. The analysis will be performed with a two-sided alpha type 1 error of 5%.

Burden and risks associated with participation: Participation within the study includes a minimal burden, since no additional blood samples will be taken compared to standard of care when treated with gemcitabine monotherapy. Follow-up visits also reflect standard of care. Patients will be asked to answer quality of life questionnaires during treatment and follow-up.

Relevance: Each year approximately 900 patients are diagnosed with LAPC in the Netherlands. Current treatment options provide only a marginal survival benefit and FOLFIRINOX (a combination of 5-fluorouracil, leucovorin, oxaliplatin and irinotecan) treatment shows high toxicity rates. Although no comparative studies have been done, nab-paclitaxel plus gemcitabine seems to give less toxicity. Superiority of nab-paclitaxel plus gemcitabine compared to gemcitabine monotherapy has been demonstrated in patients with metastatic pancreatic cancer. In this study we want to evaluate if this regimen is of importance in patients with LAPC as well.

Doel van het onderzoek

A disease control of 60% is expected and will be clinically relevant with a lower reference bound of 45%.

Onderzoeksopzet

- Baseline

- FU at 1, 3, 6, 9, 12 months after start of study treatment

- CT evaluation after 2 and 4 cycles

Onderzoeksproduct en/of interventie

chemotherapy treatment with nab-paclitaxel plus gemcitabine

Contactpersonen

Publiek

UMCU/AMC
Lilly Brada
Utrecht
The Netherlands
0031682139024

Wetenschappelijk

UMCU/AMC
Lilly Brada
Utrecht
The Netherlands
0031682139024

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Written informed consent according to ICH/GCP, and national/local regulations prior to any screening procedures.

• Histological or cytological confirmed diagnosis of pancreatic ductal adenocarcinoma.

• Locally advanced pancreatic cancer according to DPCG criteria (SMA, celiac axis or CHA contact >90° or SMV-PV contact <270° or occlusion)

• ECOG (WHO) performance status 0-2

• Age ≥ 18 years

• Adequate bone marrow and organ function as defined by the following laboratory values:

• Absolute neutrophil count (ANC) ≥ 1.5 *109 / L

• Hemoglobin (Hb) ≥ 9.0 g/dL (5.6 mmol/L)

• Platelets ≥ 100 *109/L

• Serum total bilirubin within ≤ 1.5 x ULN (upper limit of normal); or total bilirubin < 3.0 x ULN with direct bilirubin within normal range in patients with well documented Gilbert’s syndrome.

• Creatinine clearance > 50 ml / min / 1.73 m2

• AST and ALT < 2.5 ULN

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• ECOG (WHO) performance status ≥ 3

• Distant metastases on abdominal or thoracic CT scan.

• Previous surgical, local ablative, chemotherapy or radiotherapy for pancreatic cancer except for a surgical exploration with no options for resection.

• Pregnancy

• Patients who in the investigators' opinion may be unwilling, unable or unlikely to comply with requirements of the study protocol

• Patients who are not willing to avoid consumption of seville oranges, grapefruit or grapefruit juice grapefruit hybrids, pommelos and exotic citrus fruits during the entire study and preferably 7 days before the first dose of study medications, due to potential CYP3A4 interaction with the study medications.

• Patient is currently being treated with drugs known to be strong inhibitors or inducers of CYP3A4 or CYP2C8, which cannot be discontinued or switched to a different medication 7 days prior to starting study treatment and for the duration of the study

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-09-2017
Aantal proefpersonen:	136

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 24-08-2017

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	NL6467
NTR-old	NTR6645
Ander register	EudraCT: 2016-001332-35; Celgene: AX-CL-PANC-PI-0006859 : CCMO: NL59412.018.16

Resultaten

Samenvatting resultaten
not yet