A nationwide open-label multi-center prospective cohort study of nab-paclitaxel plus gemcitabine in patients with locally advanced pancreatic cancer

Published: 13-01-2017
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To investigate disease control after nab-paclitaxel plus gemcitabine in patients with locally advanced pancreatic cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON46852

Source
ToetsingOnline

Brief title
NABGEM studie

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
'pancreatic adenocarcinoma' 'pancreatic cancer'

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Celgene,Celgene

Corporation

Intervention

Keyword: Locally advanced, Nab-paclitaxel, Pancreatic cancer

Outcome measures

Primary outcome

Disease control (non-progressive disease according to RECIST 1.1 criteria)

after 2 cycles, confirmed after 4 cycles.

Secondary outcome

Toxicity, progression-free survival, overall survival, tumor marker response,

resection rate and quality of life.

Study description

Background summary

In the Netherlands, around 2300 patients are diagnosed with pancreatic cancer each year.1 It is estimated that 30 - 40 % of patients have *locally advanced pancreatic cancer (LAPC)*: i.e. locally irresectable disease due to encasement of vascular structures, without distance metastasis.The prognosis has barely improved in the last decades and pancreatic cancer-related death is still increasing. 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.

Study objective

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

Study design

The study is designed as an open-label multicenter prospective cohort study. All patients that are eligible for the study will be treated with the

combination of nab-paclitaxel plus gemcitabine. We aim to include 136 patients.

Intervention

nab-paclitaxel plus gemcitabine chemotherapy

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2017
Enrollment:	136
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	abraxane
Generic name:	nab-paclitaxel
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	13-01-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	20-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	15-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	02-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	12-03-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	14-08-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-04-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2016-001332-35-NL
CCMO	NL59412.018.16

Study results

Date completed:	31-01-2020
Actual enrolment:	15

Summary results
Trial ended prematurely