An open-label phase 1b study to evaluate the safety and efficacy of CCX872-B in patients with pancreatic adenocarcinoma.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42021

Source
ToetsingOnline

Brief title
Treatment of pt with pancreatic adenocarcinoma with CCX872-B.

Condition

- Other condition

Synonym
pancreatic adenocarcinoma, Pancreatic cancer

Health condition

alvleesklier

Research involving

Human

Sponsors and support

Primary sponsor: Chemocentryx
Source(s) of monetary or material Support: ChemoCentryx;Inc.

Intervention

Keyword: CCX872-B, Oncology, Pancreatic adenocarcinoma, Phase 1b

Outcome measures

Primary outcome

The primary efficacy endpoint is progression-free survival, based on RECIST 1.1 when all patients have completed at least 24 weeks (Day 169) in Part B of the study.

Secondary outcome

Secondary efficacy endpoints:

1. Change from baseline to Day 85 (and other available time points) in the tumor density of CCR2-positive celles, myoloid cells, tumor-associated macrophages, and effector cells.

2. The tumor control rate (TCR) as defined by stable disease, partial response and complete response.

3. Overall patient survival when all patients have completed at least 24 weeks.

4. Change from baseline to Day 85 (and other available time points) in cytokine expression profile in tumor samples based on protein or gene expression changes of cytokines.

Study description

Background summary

CCX872-B is an investigational medication for the treatment of patients with pancreatic cancer. It works by blocking the infiltration of cells of the immune system into the tumor that are thought to block the part of your immune system that can fight the cancer cells.

An investigational medication is a medication or a formulation of a medication that is still being studied. It has not been approved by the US Food and Drug Administration, the European Medicines Agency or any of the Regulatory authorities in the European countries.

This investigational medication is being developed by ChemoCentryx, Inc., which is the Sponsor of this study and pays for the study.

Study objective

The study will be conducted in two parts, Part A and Part B. The main purpose of Part A of the study is to evaluate the safety and tolerability, the blood levels and the extent of receptor blockade of CCX872-B in patients with pancreatic cancer. In this part of the study (Part A), the efficacy will not be evaluated.

CCX872-B is provided in a tablet form and will be taken by mouth. In Part A, subjects will receive a single dose of CCX872-B.
Part B of the study will only start after the results of Part A were analyzed and after, based on these results, it was concluded that it is safe and appropriate to proceed. The purpose of Part B is to determine whether the investigational medication CCX872-B is safe in patients with pancreatic cancer who also receive standard FOLFIRINOX chemotherapy, when administered over a period of at least 12 weeks, and whether it slows down the progression of the disease.
Subjects who participate in Part A may be eligible for Part B, if they are candidates for FOLFIRINOX chemotherapy.

Study design

Part A: This part of the study consists of a single dose of treatment with CCX872-B followed by a 7-day follow-up period.

You will be asked to take the dose of study medication while you are at the study center, in the presence of the study staff.

Part B: You will receive CCX872-B 150 mg once or twice daily starting on Day 1 and will continue dosing for at least 12 weeks (84 days). The study visits during this 12-week treatment period are Days 1, 8, 15, 29, 43, 57, 71, and 85, with a 4-week follow-up period after end of treatment (Day 113).

If you show at least stable disease according to a validated tumor evaluation method (called RECIST 1.1) at the end of the 12-week period (Day 85), you are eligible for continuation of CCX872-B treatment until disease progression or until you experience unacceptable toxicity.

In this case and if you agree to continue CCX872-B treatment beyond Day 85, you will need to continue to visit the study center at Day 1 and 15 of each 28-day cycle.

In Part B you will receive your first regimen of FOLFIRINOX chemotherapy on Study Day 1.
The FOLFIRINOX chemotherapy is for treatment of pancreatic cancer and is not investigational (not experimental). It consists of oxaliplatin 85 mg/m2 IV, irinotecan 180 mg/m2 IV, leucovorin 400 mg/m2 IV, and 5-FU 400 mg/m2 bolus, followed by 2400 mg/m2 by central IV infusion over 46 hours starting on Day 1. The FOLFIRINOX chemotherapy will be repeated every 2 weeks for up to 12 cycles.

Intervention

Not applicable.

Study burden and risks

CCX872-B has been evaluated in healthy subjects. The most common side effect reported after a single dose in this study was headache in 7% of subjects. The most common side effects reported after multiple daily doses in this study were diarrhea (13%), stuffy nose (13%), dizziness (13%) and headache (10%). No hospitalizations due to side effects occurred in this study.

It is possible that unforeseen adverse events may occur. The patient will be monitored carefully during the study for any adverse effects.
During the collection of blood samples, the patient may experience pain and/or bruising at the insertion site of the needle/indwelling cannula. Although rare, localized clot formation and infections at the injection site may occur. Lightheadedness and/or fainting may also occur during or shortly after the blood draw.

ECG patches may cause a skin reaction such as redness or itching. The patient may also experience localized skin discomforts and/or hair loss associated with the placement of ECG leads.

Additional risks for participants in Part B:

FOLFIRINOX may cause low red blood cell counts, low platelet counts, low white blood cell counts, tiredness, vomiting, diarrhea , nervous system toxicity, elevated liver enzymes, and blood clots.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Have histologically or cytologically confirmed pancreatic adenocarcinoma.;2. Eastern Cooperative Oncology Group (ECOG) performance status score <= 2.;3. Male or female subjects, aged at least 18 years; Female subjects of childbearing potential and male subjects with female partners of childbearing potential using adequate contraception. See also page 37 of the protocol.;4. Anticipated life expectancy >= 12 weeks.;5. Ability to provide written

informed consent and comply with the requirements of the study protocol.;In part B of the study , subjects must additionally meet these entry criteria:;6. Have non-resectable pancreatic adenocarcinoma with or without metastases. ;7. Have radiographically measureable disease according to RECIST 1.1.

Exclusion criteria

1. Received other cancer treatment or any investigational drug within 4 weeks prior to screening.;2. Women who are pregnant or breastfeeding.;3. Had major surgery within 4 weeks of the first dose of study drug.;4. Inadequate liver, renal, or bone marrow function within 2 weeks before first dosing.;5. Serious concurrent illness, altered mental status or any uncontrolled medical condition.;6. Any infection requiring antibiotic or anti-viral treatment within 4 weeks of screening.;7. Known active HIV, HBV or HCV infection.;8. Taking agents known to be strong inhibitors or inducers of CYP3A4 or UGT1A1 within 2 weeks of Day 1 dosing; these include atazanavir, boceprevir, clarithromycin, conivaptan, gemfibrozil, grapefruit juice, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole, rifampin, and carbamazepine; use of these drugs must be avoided during the study and until 2 weeks after stopping CCX872-B treatment.;9. Taking any other test drug within 3 weeks or 5 half-lives (whichever is longer) prior to Day 1 of the study;;10. Inability to swallow tablets.;11. History or presence of any medical condition or disease which may place the subject at unacceptable risk for study participation.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-04-2015
Enrollment:	29
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	CCX872-B
Generic name:	CCX872-B

Ethics review

Approved WMO Date:	27-11-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-02-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	21-04-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-09-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-09-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	EUCTR2014-004406-15-NL
CCMO	NL51406.078.15