A Phase III Study of BBI-608 plus nab-Paclitaxel with Gemcitabine in Adult Patients with Metastatic Pancreatic Adenocarcinoma.

Published: 21-03-2017
Last updated: 15-04-2024

To compare overall survival (OS) of patients with metastatic (Stage IV) PDAC treated with BBI-608 plus weekly nab-paclitaxel with gemcitabine versus weekly nab-paclitaxel with gemcitabine.

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

Summary

ID

NL-OMON50631

Source
ToetsingOnline

Brief title
CanStem111P

Condition

- Metastases

Synonym
Metastatic Pancreatic Ductal Adenocarcinoma (PDAC)

Research involving
Human

Sponsors and support

Primary sponsor: Sumitomo Dainippon Pharma Oncology, Inc.

Source(s) of monetary or material Support: Boston Biomedical;Inc.

Intervention

Keyword: BBI-608, Metastatic, Pancreatic Adenocarcinoma, phase III

Outcome measures

Primary outcome

To compare overall survival (OS) of patients with metastatic (Stage IV) PDAC treated with BBI-608 plus weekly nab-paclitaxel with gemcitabine versus weekly nab-paclitaxel with gemcitabine.

Secondary outcome

Key Secondary Objectives

* To compare Progression-Free Survival (PFS) in patients with metastatic PDAC treated with BBI-608 plus weekly nab-paclitaxel with gemcitabine versus weekly nab-paclitaxel with gemcitabine.

* To compare Disease Control Rate (DCR) in patients with metastatic PDAC treated with BBI-608 plus weekly nab-paclitaxel with gemcitabine versus weekly nab-paclitaxel with gemcitabine.

* To compare Overall Response Rate (ORR) in patients with metastatic PDAC treated with BBI-608 plus weekly nab-paclitaxel with gemcitabine versus weekly nab-paclitaxel with gemcitabine.

Other Secondary Objectives

* To evaluate the safety profile of BBI-608 administered daily plus weekly nab-paclitaxel and gemcitabine in patients with metastatic PDAC with safety assessed according to the National Cancer Institute Common Toxicity Criteria

for Adverse Events (NCI CTCAE) version 4.0.

* To compare the Quality of Life (QoL), as measured using the European Organization for Research and Treatment of Cancer Quality of Life questionnaire (EORTC-QLQ-C30), in patients with metastatic PDAC treated with BBI-608 plus weekly nab-paclitaxel with gemcitabine versus weekly nab-paclitaxel with gemcitabine.

Study description

Background summary

Pancreatic ductal adenocarcinoma (PDAC) is the most common form of pancreatic cancer with the worst prognosis of all solid tumors. Surgery is considered the only potentially curative treatment, however, more than 80% of patients present with locally advanced or metastatic disease. Out of the minority of presenting patients who qualify for curative surgery, most will develop disseminated advanced disease with a 5-year survival rate of less than 5%.

Standard treatment for unresectable and metastatic disease currently includes first-line combination regimen with FOLFIRINOX (5-FU, leucovorin, irinotecan and oxaliplatin), a regimen that provides a median overall survival (OS) of 11.1 months in patients with treatment-naïve disease. Moreover, a number of uncontrolled studies have shown that modified FOLFIRINOX (mFOLFIRINOX) regimen results in decreased toxicity while maintaining efficacy in patients with pancreatic adenocarcinoma. Most recently, a liposomal irinotecan formulation was shown to improve overall survival by 3 months (8.9 months vs 5.9 months) in combination with 5-FU and leucovorin in patients with metastatic PDAC progressing on gemcitabine-based first-line treatment as compared to patients treated with 5-FU and leucovorin alone.
Currently, a patient with advanced disease progressing in first-line therapy has limited treatment options. Given the morbidity associated with this disease, there is an urgent need to identify novel therapies to improve the outcome of patients with advanced unresectable PDAC.

CSCs or cancer cells with stemness phenotypes are a sub-population of cancer cells that have self-renewal capability, are highly malignant and are considered to be fundamentally responsible for malignant growth, recurrence, drug-resistance and metastasis. Moreover, CSCs are highly resistant to chemotherapies and current targeted agents. CSCs have been isolated from almost

all major tumor types, including PDAC.
(See protocol section 2.1 and 2.2)

Napabucasin is a small molecule that is hypothesized to affect multiple oncogenic cellular pathways, including inhibition of the STAT3 pathway which has been implicated in cancer stem cell viability. CSCs are a small cancer cell population that can self-renew and are causally linked
to malignant growth and metastasis Current evidence suggests that such cells exist in almost all major tumor types, including breast, colon, and lung. CSCs give rise to the heterogeneous cancer cells that form the bulk tumor mass and phenotypically characterize the disease. CSCs and non-stem cancer cells appear to have different biologic characteristics.

CSCs have been shown to contribute to malignant growth, cancer metastasis, recurrence, and
cancer drug resistance. Therefore, targeting of CSCs is being explored as a cancer treatment.
Napabucasin has demonstrated in vitro activity against CSCs in cell line models of human cancer
(Reference from IB section 1: summary)
(For more information please see Investigator*s brochure section 4.1.1.7).

BBI-608 at a dose of 240 mg BID (480 mg total daily) combined with a standard regimen of gemcitabine and nab-paclitaxel was tolerated in patients with advanced pancreatic cancer. The clinical activity observed in the BBI608-118 (BBI608-201PANC) study, paired with the unmet medical need for additional effective therapies in pancreatic cancer, provides a rationale for further clinical investigation. CanStem111P is designed to evaluate the role of BBI-608 in combination with nab-paclitaxel and gemcitabine as frontline therapy for metastatic PDAC.
(See protocol section 2.1 to 2.4)

Study objective

To compare overall survival (OS) of patients with metastatic (Stage IV) PDAC treated with BBI-608 plus weekly nab-paclitaxel with gemcitabine versus weekly nab-paclitaxel with gemcitabine.

Study design

This is a randomized, open-label, multi-center, phase III study of BBI-608 plus weekly nab-paclitaxel with gemcitabine (Arm 1) vs. weekly nab-paclitaxel with gemcitabine (Arm 2) for adult patients with metastatic PDAC.
1132 patients will be randomized in a 1:1 ratio, stratified according to geographical region (North America/Western Europe/Australia vs. Japan/Korea vs. Rest of the World), Eastern Cooperative Oncology Group (ECOG) performance

status (0 vs. 1), and presence of liver metastases (yes vs. no). Enrollment was completed prior to this amendment.
Until the time of this amendment, the study proceeded in 28-day (4-week) cycles. BBI-608 was administered orally, twice daily, with doses separated by approximately 12 hours. BBI-608 administration began 2-5 days prior to the first nab-paclitaxel with gemcitabine infusion. Nab-paclitaxel 125 mg/m2 immediately followed by gemcitabine 1000 mg/m2 were administered on Days 1, 8 and 15 of every 28-day cycle via intravenous infusion.

From the time of this amendment, and since the outcome of the interim analysis which was futile, patients may continue protocol therapy if it is believed to be in their best interest by the investigator and patient, and with the patient*s informed consent. Patients will receive BBI-608, nab-paclitaxel and/or gemcitabine at the same dose and schedule that they were receiving prior to the amendment. Patients on Arm 1 may continue BBI-608 with the Sponsor*s approval. Patients on Arm 1 may also discontinue BBI-608 but choose to continue with nab-paclitaxel and gemcitabine alone.

Tumor assessments will be performed every 8 weeks after randomization until objective disease progression or treatment discontinuation due to toxicity.
The protocol will continue to be followed for all endpoints until study completion. The study is planned for completion on February 28th, 2020.

Intervention

Arm 1:
Until the time of this amendment, patients randomized to Arm 1 on this study received BBI-608 orally, daily, at 240 mg bid (480 mg total daily dose).
BBI-608 was taken daily continuously throughout each 4 week (28 day) study cycle in combination with nab-paclitaxel and gemcitabine. BBI-608 was administered twice daily, one hour prior or two hours after meals, with the first dose taken in the morning and doses separated by approximately 12 hours.
Patients randomized to Arm 1 received BBI-608 in combination with nab-paclitaxel and gemcitabine.

Arm 2:
Patients randomized to Arm 2 received nab-paclitaxel and gemcitabine alone.
Nab-paclitaxel 125 mg/m2 was administered intravenously starting on Day 1 of Cycle 1. Gemcitabine 1000 mg/m2 was administered intravenously following nab-paclitaxel infusion. This regimen was repeated on Days 1, 8 and 15 of every 28-day cycle.
Dose modification of BBI-608 and/or nab-paclitaxel and/or gemcitabine was allowed. There were no dose reductions or adjustments for lymphopenia or alopecia.

From the time of this amendment, and since the outcome of the interim analysis was communicated to investigators, patients may continue protocol therapy if it

is believed to be in their best interest by the investigator and patient, and with the patient*s informed consent. Patients will receive BBI-608, nab-paclitaxel and/or gemcitabine at the same dose and schedule that they were receiving prior to the amendment. Patients on Arm 1 may continue BBI-608 with the Sponsor*s approval. Patients on Arm 1 may discontinue BBI-608 but choose to continue with nab-paclitaxel and gemcitabine

Study burden and risks

As with any clinical study there is the risk of a new investigational drug, and minor risk of intrusion.

Although all necessary steps will be taken to protect the subject's confidential information there is a minor risk of breach of confidentiality. Staff at each site will be trained on the importance of confidentiality and this will also be discussed in the confidentiality section of the informed consent document.

Even though patient information sheets will be translated into appropriate language, there is a possibility of misunderstanding.
There is a risk that addition of the investigational drug to the standard of care may not have any additional benefit to the participant. There is also the risk of having a rare but severe allergic reaction due to the investigational drug. There may be other risks in the combination treatment that we do not know about. Safety procedures and visits are in place to monitor the risks. A DSMB will also review study data periodically and make recommendations to ensure continued subject safety.

Taking part in a clinical trial adds the burden of frequent visits for dosing of the study drug and a few additional research procedures, e.g. blood tests. Subjects will need to understand this and must agree. Home visits may be conducted in lieu of on-site visits per institutional standards.

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

Patients must fulfill all of the following criteria to be eligible for admission to the study:, 4.1.1. Written, signed consent for trial participation must be obtained from the patient appropriately in accordance with applicable ICH guidelines and local and regulatory requirements prior to the performance of any study specific procedure., 4.1.2. Must have histologically or cytologically confirmed advanced PDAC that is metastatic. The definitive diagnosis of metastatic PDAC will be made by integrating the histopathological data within the context of the clinical and radiographic data. Patients with islet cell neoplasms are excluded., 4.1.3. Must not have previously received chemotherapy or any investigational agent for the treatment of PDAC.
* A fluoropyrimidine or gemcitabine administered as a radiation sensitizer in the adjuvant setting is allowed for as long as last dose was administered > 6 months prior to randomization and no lingering toxicities are present., 4.1.4. Nab-paclitaxel with gemcitabine therapy is appropriate for the patient and recommended by the Investigator., 4.1.5. Patient has one or more metastatic tumors evaluable by CT scan with contrast (or MRI, if patient is allergic to CT contrast media) per RECIST 1.1. Imaging investigations including CT/MRI of chest/abdomen/pelvis or other scans as necessary to document all sites of disease must be performed within 14 days prior to randomization. Qualifying scans performed as part of standard of care prior to patient signature of the study informed consent will be acceptable as baseline scanning as long as scanning is performed < 14 days prior to randomization., 4.1.6. Must have ECOG Performance Status of 0 or 1, assessed within 14 days prior to randomization. Two observers qualified to perform assessment of the performance status will be

required to perform this assessment. If discrepant, the one with the most deteriorated performance status will be considered true.
* Patients must not require any help with activities of daily living (ADLs), including eating, dressing, washing or using the toilet.
* Patients must not need to stay in bed or chair for 50% or more of waking hours.
* Patients with factors that limit accurate assessment of performance status will not be eligible for the study. This includes but is not limited to patients with pre-existing conditions preventing them from full mobility (including but not limited to spinal or orthopedic conditions, amputees, morbid obesity defined by BMI > 40)., 4.1.7. Must have life-expectancy of > 12 weeks., 4.1.8. Must be * 18 years of age.
* Due to increased risk of sepsis in patients >80 years old, candidate patients in this age group should be thoroughly evaluated prior to study randomization to ensure they are fit to receive chemotherapy. In addition to all of the inclusion/exclusion criteria listed, clinical judgment should be used regarding patients* susceptibility to infection (including but not limited to presence of ascites or diabetes mellitus increasing risk of infection). Furthermore, the expected stability of their performance status while receiving repeat weekly chemotherapy cycles should be given special attention. Patients in this age group should not be randomized on the study should there be any hesitation on any of these considerations., 4.1.9. For male or female patients of child producing potential: Must agree to use contraception or take measures to avoid pregnancy during the study and for 180 days after the final dose of nab-paclitaxel and gemcitabine or for 30 days for female patients and for 90 days for male patients, after the final BBI-608 dose if nab-paclitaxel and gemcitabine were not administered., Adequate contraception is defined as follows:
1. Complete true abstinence: when this is in line with the preferred and usual lifestyle of the subject.
2. Consistent and correct use of one of the following methods of birth control:
a. male partner who is sterile prior to the female subjects entry into the study and is the sole sexual partner for that female subject; or
b. implants of levonorgesterol; or
c. injectable progestagen; or
d. any intrauterine device (IUD) with a documented failure rate of less than 1% per year; or
e. any intrauterine hormone-releasing system (IUS) with a documented failure rate of less than
1% per year; or
f. oral contraceptive pill (either combined or progesterone only); or
g. one barrier method, for example diaphragm with spermicide or condom with spermicide in combination with either implants of levonorgesterol or injectable progestagen, any intrauterine device (IUD) or intrauterine hormone-releasing system (IUS) with a documented failure rate of less than 1% per year, or oral contraceptive pill (either combined or progesterone only)., 4.1.10. Women of child bearing potential (WOCBP) must have a negative serum or urine pregnancy

test within 5 days prior to randomization. The minimum sensitivity of the pregnancy test must be 25 IU/L or equivalent units of human chorionic gonadotropin (HCG)., WOCBP include any female who has experienced menarche and who has not undergone successful surgical sterilization (hysterectomy, bilateral tubal ligation or bilateral oophorectomy) or is not postmenopausal (defined as amenorrhoea > 12 consecutive months; or women on hormone replacement therapy (HRT) with documented serum follicle stimulating hormone (FSH) level > 35 mIU/mL). Even women who are using oral, implanted or injectable contraceptive hormones or mechanical products such as an intrauterine device or barrier methods (diaphragm, condoms, spermicides) to prevent pregnancy or practicing abstinence or where partner is sterile (e.g. vasectomy), should be considered to be of child bearing potential., 4.1.11. Patient has adequate biological parameters as demonstrated by the following blood counts at baseline (obtained < 14 days prior to randomization; laboratory testing performed as part of standard of care prior to patient signature of informed consent for the study will be acceptable as baseline laboratory work as long as testing is performed < 14 days prior to randomization):
* Absolute neutrophil count (ANC) > 1.5 x 109/L
* Platelet count > 100,000/mm3 (100 x 109/L). Must not have required transfusion of platelets within 1 week of baseline platelet count assessment
* Hemoglobin (HgB) > 9 g/dL. Must not have required transfusion of red blood cells within 1
week of baseline Hgb assessment, 4.1.12. Patient has the following blood chemistry levels at baseline (obtained < 14 days prior to randomization; laboratory testing performed as part of standard of care prior to patient signature of informed consent for the study will be acceptable as baseline laboratory work as long as testing is performed < 14 days prior to randomization):
* AST (SGOT) and ALT (SGPT) * 2.5 × institutional upper limit of normal (ULN) [* 5 × ULN in presence of liver metastases]
* Total bilirubin * 1.5 x institutional ULN. If total bilirubin is > ULN and < 1.5 x ULN, it must be non-rising
for at least 7 days
* Serum creatinine within normal limits or calculated clearance > 60 mL/min/1.73 m2 for patients with serum creatinine levels above or below the institutional normal value. If using creatinine clearance, actual body weight should be used for calculating creatinine clearance (eg. Using the Cockroft-Gault formula). For patients with a Body Mass Index (BMI) > 30 kg/m2, lean body weight should be used instead., 4.1.13. Patient not on anticoagulation has acceptable coagulation studies (obtained < 14 days prior to randomization; laboratory testing performed as part of standard of care prior to patient signature of informed consent for the study will be acceptable as baseline laboratory work as long as testing is performed < 14 days prior to randomization) as demonstrated by prothrombin time (PT) and partial thromboplastin time (PTT) below or within normal limits (+15%).
* Patients on anticoagulation must have coagulation values within the therapeutic range

appropriate for the anti-coagulation indication, 4.1.14. Patient has no clinically significant abnormalities on urinalysis results (obtained < 14 days prior to randomization; laboratory testing performed as part of standard of care prior to patient signature of informed consent for the study will be acceptable as baseline laboratory work as long as testing is performed < 14 days prior to randomization). , 4.1.15. Patient must have adequate nutritional status with Body Mass Index (BMI) > 18 kg/m2 and body weight of > 40 kg with serum albumin > 3 g/dL., 4.1.16. Baseline laboratory evaluations must be done within 14 days prior to randomization and some must be repeated < 72 hours prior to randomization, as listed in Section 6.0. , 4.1.17. Patients requiring biliary stent placement must have biliary stent placed > 7 days prior to screening. , 4.1.18. Pain symptoms should be stable (of tolerable Grade 2 or less)., 4.1.19. Only patients with available archival tumor tissue must consent to provision of, and Investigator(s) must confirm access to and agree to submit a representative formalin fixed paraffin block of tumor tissue in order that the specific correlative marker assays proscribed in Section 13.6 (Correlative Studies) of this protocol may be conducted. Submission of the tissue does not have to occur prior to randomization. Where local center regulations prohibit submission of blocks of tumor tissue, two 2 mm cores of tumor from the block and 5-20 unstained slides of whole sections of representative tumor tissue are preferred. Where it is not possible to obtain two 2 mm cores of tumor from the block, 5-20 unstained slides of representative tumor tissue are also acceptable. Where no previously resected or biopsied tumor tissue exists or is available, on the approval of the Sponsor/designated CRO, the patient may still be considered eligible for the study., 4.1.20. Patient must consent to provision of a sample of blood in order that the specific correlative marker assays proscribed in Section 13.6 (Correlative Studies) may be conducted., 4.1.21. Patients must be accessible for treatment and follow up. Patients registered on this trial must receive protocol treatment and be followed at the participating center. This implies there must be reasonable geographical limits placed on patients being considered for this trial. Investigators must ensure that the patients randomized on this trial will be available for complete documentation of the treatment, response assessment, adverse events, and follow-up., 4.1.22. Protocol treatment is to begin within 2 calendar days of patient randomization for patients randomized to Arm 1. Patients randomized to Arm 2 must begin protocol treatment within 7 calendar days of randomization., 4.1.23. The patient is not receiving therapy in a concurrent clinical study and the patient agrees not to participate in other interventional clinical studies during their participation in this trial while on study treatment. Patients participating in surveys or observational studies are eligible to participate in this study.

Exclusion criteria

Patients who fulfill any of the following criteria are not eligible for

admission to the study:, 4.2.1. Patients with no evidence of metastatic disease as well as patients with a local recurrence following surgical resection of primary lesion., 4.2.2. Patient has experienced a decline in ECOG performance status between Baseline visit and within 72 hours prior to randomization., 4.2.3. Patient has a > 20% decrease in serum albumin level between Baseline visit and within 72 hours prior to randomization., 4.2.4 Patient has a > 10% decrease in weight between Baseline visit and within 72 hours prior to randomization, 4.2.5. Any prior anti-cancer chemotherapy, biologic or investigational therapy for PDAC.
a. Patients receiving immunotherapy for non-cancer related treatment within * 4 weeks of first planned dose of study treatment will be excluded.
b. A fluoropyrimidine or gemcitabine administered as a radiation sensitizer in the adjuvant setting is allowed for as long as last dose was administered > 6 months prior to randomization., 4.2.6. Major surgery within 4 weeks prior to randomization., 4.2.7. Any known brain or leptomeningeal metastases are excluded, even if treated., 4.2.8. Patients with clinically significant ascites or pleural effusions., 4.2.9. Women who are pregnant or breastfeeding. Women should not breastfeed while taking study treatment and for 4 weeks after the last dose of BBI-608 or while undergoing treatment with nab-paclitaxel and gemcitabine and for 180 days after the last dose of nab-paclitaxel and gemcitabine., 4.2.10. Gastrointestinal disorder(s) which, in the opinion of the Principal Investigator, would significantly impede the absorption of an oral agent (e.g. active Crohn*s disease, ulcerative colitis, extensive gastric and small intestine resection)., 4.2.11. Unable or unwilling to swallow BBI-608 capsules daily., 4.2.12. Uncontrolled inter-current illness including, but not limited to, ongoing or active infection, clinically significant non-healing or healing wounds, symptomatic congestive heart failure, unstable angina pectoris, clinically significant cardiac arrhythmia, significant pulmonary disease (shortness of breath at rest or mild exertion), uncontrolled infection or psychiatric illness/social situations that would limit compliance with study requirements.
a. History of cardiac disease: congestive heart failure (CHF) > NYHA Class II; active coronary artery disease, myocardial infarction or coronary stenting within 6 months prior to randomization; unevaluated new onset angina within 3 months or unstable angina (angina symptoms at rest) or cardiac arrhythmias requiring anti-arrhythmic therapy (beta blockers or digoxin are permitted).
b. Current uncontrolled hypertension (systolic blood pressure [BP] > 150 mmHg or diastolic pressure > 90 mmHg despite optimal medical management) as well as prior history of hypertensive crisis or hypertensive encephalopathy.
c. Significant vascular disease (e.g., aortic aneurysm, aortic dissection, symptomatic peripheral vascular disease including claudication, Leo Buerger*s disease). Treated peripheral vascular disease that is stable for at least 6 months is allowed.
d. Evidence of bleeding diathesis or clinically significant coagulopathy.
e. Major surgical procedure (including open biopsy, significant traumatic injury, etc.) within 28 days, or anticipation of the need for major surgical procedure during the course of the study as well as minor surgical procedure

(excluding placement of a vascular access device or bone marrow biopsy) within 7 days prior to randomization.
f. Patients with clinically significant abnormalities on urinalysis at < 14 days prior to randomization.
g. History of abdominal fistula, gastrointestinal perforation, or intra-abdominal abscess within 6 months prior to randomization.
h. Ongoing serious, non-healing wound, ulcer, or bone fracture.
i. Known infection with Human Immunodeficiency Virus (HIV), and/or active infection with hepatitis B, or hepatitis C.
j. History of interstitial lung disease, history of slowly progressive dyspnea and unproductive cough, sarcoidosis, silicosis, idiopathic pulmonary fibrosis, pulmonary hypersensitivity pneumonitis or multiple allergies.
k. History of hemolytic-uremic syndrome.
l. History of connective tissue disorders (eg, lupus, scleroderma, arteritis nodosa).
m. Serious medical risk factors involving any of the major organ systems, or serious psychiatric disorders that could compromise the patient*s safety or the study data integrity., 4.2 13. Known hypersensitivity to gemcitabine, taxanes or any of their excipients, or the patient exhibits any of the events outlined in the Contraindications or Special Warnings and Precautions sections of the product or comparator SmPC or Prescribing Information. Possible hypersensitivity to BBI-608 or one of the excipients which include the azo dyes sunset yellow and allura red., 4.2.14. Neurosensory neuropathy > grade 2 at baseline., 4.2.15. Uncontrolled chronic diarrhea > grade 2 at baseline., 4.2.16. Patients being treated with Warfarin., 4.2.17. Patients with active, uncontrolled bacterial, viral or fungal infection(s) requiring systemic therapy, 4.2.18. Patients with a history of other malignancies except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer of the cervix, or other solid tumors curatively treated by surgery alone or surgery plus radiotherapy with no evidence of disease continuously for > 5 years., 4.2.19. Any active disease condition which would render the protocol treatment dangerous or impair the ability of the patient to receive protocol therapy., 4.2.20. Any condition (e.g. psychological, geographical, etc.) that does not permit compliance with the protocol, including patients with history of poor compliance or history of drug/alcohol abuse, or excessive alcohol beverage consumption that would interfere with the ability to comply with the study protocol. Patients planning to take a vacation for 14 or more consecutive days during the course of the study are ineligible.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2018
Enrollment:	4
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Abraxane
Generic name:	Nab-Paclitaxel
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	BBI-608
Generic name:	napabucasin
Product type:	Medicine
Brand name:	Gemcitabine
Generic name:	Gemcitabine
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	21-03-2017
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-10-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-03-2019
Application type:	Amendment

Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-03-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-09-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2020
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	EUCTR2016-004359-57-NL
ClinicalTrials.gov	NCT02993731
CCMO	NL60833.018.17