Studying the intratumoral concentration of CriPec® docetaxel compared to Taxotere®

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23720

Source
Nationaal Trial Register

Brief title
the CRITAX study

Health condition

All tumor types which do not have standard treatment options and who might benefit from taxane containing chemotherapy

Sponsors and support

Primary sponsor: Erasmus MC, Rotterdam
Source(s) of monetary or material Support: Cristal Therapeutics

Intervention

Outcome measures

Primary outcome

The difference in concentration of docetaxel in tumor tissue after administration of CriPec® docetaxel compared to Taxotere®.

Secondary outcome

Plasma levels of total and released (free) docetaxel after dosing; Cmax, Tmax, AUClast, AUCinf, Thalf, Cl and Vss in relation to body weight (kg). Incidence of grade 3 or 4 adverse events (AEs) during the first cycle of CriPec® docetaxel or Taxotere®.

Study description

Background summary

The current study aims to investigate the difference in the intratumoral accumulation of docetaxel in patients treated with CriPec® docetaxel and Taxotere®.

Study objective

To demonstrate a 25% increase of docetaxel in tumor tissue after intravenous administration of CriPec® docetaxel compared to Taxotere®.

Study design

Tumor biopsies will be taken 24, 48, 72 or 96 hours after each administration during cycle 1 and cycle 2. For each time point 4 patients will be included. Plasma PK samples will be taken on day 1, 2, 8, 15 and at the time of biopsy.

Intervention

Subjects will be randomized in a 1:1 ratio to receive CriPec® docetaxel in cycle 1 and Taxotere® in cycle 2 (Arm A) or Taxotere® in cycle 1 and CriPec® docetaxel in cycle 2 (Arm B). Both CriPec® docetaxel and Taxotere® will be administered at a dose of 75 mg/m2 (4-weekly, Q4W) and Taxotere® at a dose of 75mg/m2 (3-weekly, Q3W). After completion of cycle 2, a radiographic evaluation will take place and the patients will go off study. Subjects without evidence of disease progression or drug related toxicity can continue treatment with Taxotere® (75mg/m2, Q3W) according to local standard guidelines for Taxotere® treatment until disease progression or unacceptable toxicity occurs.

Contacts

Public
Erasmus MC, Cancer Institute, Doctor Molewaterplein 40, 3015 GD Rotterdam
F. Atrafi
Rotterdam 3075 EA

The Netherlands
0031640611843
Scientific
Erasmus MC, Cancer Institute, Doctor Molewaterplein 40, 3015 GD Rotterdam
F. Atrafi
Rotterdam 3075 EA
The Netherlands
0031640611843

Eligibility criteria

Inclusion criteria

• Age ≥ 18 years at signing of Informed Consent Form (ICF).

• Eastern Cooperative Oncology Group (ECOG) Performance Status 0 or 1.

• Estimated life expectancy of at least 12 weeks.

• Ability and willingness to give written informed consent and to comply with the requirements of the study.

• Patients with pathologically confirmed diagnosis of advanced, recurrent and progressive cancer with measurable disease according to RECIST 1.1 [Appendix 3] of a histological type that are refractory to standard therapy or for whom no standard therapy exists and where treatment with a taxane is an appropriate treatment option. This includes, but is not limited to, oesophageal, stomach, prostate, bladder, breast, head and neck, ovarian and non-small cell lung cancer.

• Willing to undergo repeated tumor biopsies

Exclusion criteria

• Less than 4 weeks since the last treatment of chemotherapy, biological therapy, immunotherapy or systemic radiotherapy (except palliative radiation delivered to <20% of bone marrow), and less than 6 weeks for nitrosoureas and mitomycin C prior to Cycle 1 Day 1.

• Current or recent (within 4 weeks prior to Cycle 1 Day 1) treatment with another Investigational Product or participation in another investigational interventional study.

• Symptomatic brain metastases.

• Toxicities incurred as a result of previous anti-cancer therapy (radiation therapy, chemotherapy, or surgery) that have not resolved to ≤ grade 2 [as defined by CTCAE version 4.03] except skin toxicity, this should be grade 0 at the base line.

Abnormal lab results which could indicate inadequate bone marrow function, as evidenced by any of the following:

• Absolute Neutrophil Count (ANC) < 1.5 x 109/L.

• Platelet count < 100 x 109/L.

• Hemoglobin < 6.0 mmol/L (<9.6 g/dL).

The patient may not have received a transfusion or growth factors for these abnormalities in the 7 days prior to Cycle 1 Day 1.

Inadequate liver function as evidenced by any of the following:

• Serum (total) bilirubin > 1.5 x the Upper Limit of Normal (ULN) for the institution if no liver metastases (> 2 x ULN in patients with liver metastases).

• AST or ALT > 2.5 x ULN if no liver metastases (> 5x ULN in patients with liver metastases).

• Hepatitis B surface antigen or hepatitis C positivity in combination with abnormal liver function tests if it is indicated to be determined by the Investigator.

Medical history of:

• Non-alcoholic steatohepatitis (NASH).

• History of human immunodeficiency virus (HIV) antibody positive or use of antiretroviral therapy.

• Alcoholic and autoimmune hepatitis.

• Ischemic hepatitis, Cardiovascular dysfunction or impaired liver oxygenation (e.g. due to hypotension or right heart failure).

• Any type of skin disease for which systemic corticosteroids is mandatory.

Inadequate renal function as evidenced by any of the following:

• Serum creatinine > 1.5 x ULN.

• Estimated Glomerular Filtration Rate of < 50 mL/min/1.73m2 calculated by Modification of Diet in Renal Disease (MDRD) formula or creatinine clearance of < 50 mL/min calculated by Cockcroft-Gault.

Clinically significant (i.e. active) cardiovascular disease as evidenced by any of the following:

• Stroke within 6 months prior to Cycle 1 Day 1.

• Transient Ischemic Attack (TIA) within 6 months prior to Cycle 1 Day 1.

• Myocardial infarction within 6 months prior to Cycle 1 Day 1.

• Unstable angina.

• New York Heart Association (NYHA) Grade II or greater Congestive Heart Failure at screening [The Criteria Committee of the New York Heart Association 1994].

• Serious cardiac arrhythmia requiring medication.

Other:

• Patients who are pregnant or breastfeeding; serum pregnancy test will be made before start of each cycle

• Absence of effective means of contraception on Cycle 1 Day 1 in female patients of childbearing potential (defined as <2 years after last menstruation and not surgically sterile) or in male patients who are not surgically sterile and who have female partners of childbearing potential.

• Major surgical procedure (including open biopsy and excluding central line intravenous catheter) within 28 days prior to Cycle 1 Day 1, or anticipation of the need for major surgery during the course of the study treatment.

• Grade ≥2 motor or sensory neuropathy symptoms [as defined by CTCAE version 4.03, Appendix 4].

• Known hypersensitivity to any of the Investigational Product’s excipients or taxanes.

• History of drug or alcohol abuse in the opinion of the Investigator within 3 years before

screening.

• Evidence of any other medical conditions (such as psychiatric illness, infectious diseases, physical examination or laboratory findings) that may interfere with the planned treatment, affect patient compliance or place the patient at high risk for treatment-related complications.

• Unable or unwilling to stop the use of (over the counter) medication of (herbal) supplements which can interact with docetaxel e.g. by induction or inhibition of CYP3A4, grapefruit containing food or juice or St. John’s Wort from 7 days before until one day after the trial.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2017
Enrollment:	16
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
Data can be requested by emailing the investigator

Ethics review

Positive opinion

Date:	29-03-2017
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	NL6299
NTR-old	NTR6474
Other	METC Erasmus MC Rotterdam : MEC-2017-025

Study results

Summary results
Manuscript in preparation