Phase 0 proof of concept trial: determination of the pharmacokinetics after administration of a microdose gemcitabine

Gepubliceerd: 09-12-2016 Laatst bijgewerkt: 13-12-2022

The pharmacokinetics of a therapeutic dose of gemcitabine can be adequatly predicted from the pharmacokinetics of a microdose

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21758

Bron
NTR

Aandoening

a. Locally advanced or metastatic non-small cell lung cancer.
b. Locally advanced or metastatic epithelial ovarian carcinoma.
c. Locally advanced or metastatic adenocarcinoma of the pancreas.
d. Locally advanced or metastatic bladder cancer.
e. Locally advanced or metastatic, inoperable breast cancer, as combination therapy with paclitaxel, when anthracyclines are ineffective or contraindicated.

Ondersteuning

Primaire sponsor: Antoni van Leeuwenhoek hospital
Overige ondersteuning: Antoni van Leeuwenhoek hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study parameters will be the concentration of gemcitabine in patient plasma. Pharmacokinetic parameters will be calculated from the acquired data.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a phase 0 prospective, single-center, open-label microdosing study. Eligible patients receive a microdose (100 ìg) on day 1 and a therapeutic dose (1000 – 1250 mg/m2) of gemcitabine on day 2. The therapeutic dosage that is given on the second day of the study is not part of the study medication as patients receive gemcitabine therapy as part of standard medical care. Blood will be drawn for pharmcokinetic reserach at 11 time points a day. The pharmacokinetic profile of the microdose will be compared to the pharmacokinetic profile of the therapeutic dose.

Doel van het onderzoek

The pharmacokinetics of a therapeutic dose of gemcitabine can be adequatly predicted from the pharmacokinetics of a microdose

Onderzoeksopzet

Blood will be drawn at both day 1 and day 2 at the following timepoints:

t=0 (predose), t=15 min (1/2th of infusion), t=30 min (end of infusion), t=45 min, t=60 min, t=75 min, t=90 min, t=105 min, t=2 h, t=4 h, t=8 h.

Onderzoeksproduct en/of interventie

Administration of a microdose (100 ug) of gemcitabine

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 18 years.

2. Indication for treatment with gemcitabine.

3. Histologically or cytologically confirmed diagnosis of:

a. Locally advanced or metastatic non-small cell lung cancer.

b. Locally advanced or metastatic epithelial ovarian carcinoma.

c. Malign mesothelioma

4. Able and willing to give written informed consent.

5. WHO performance status of 0 or 1.

6. Able and willing to undergo blood sampling for PK analysis.

7. All toxicities related to prior treatment should have resolved to CTCAE grade 1 or less.

8. Willing and able to comply with study restrictions and to remain at the study center for the required duration
.
9. Adequate organ system function.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects will not be eligible for study entry if any of the following criteria are met:

1. Prior chemotherapy, radiotherapy, radio immunotherapy, or immunotherapy within 7 days of the first dose of study treatment

2. Known hypersensitivity to gemcitabine.

3. Presence of known brain metastases or active central nervous system (CNS) disease.

4. Prior treatment with gemcitabine within 30 days of the first dose.

5. New York Heart Association Class 3 or 4 heart disease, active ischemia, or any uncontrolled, unstable cardiac condition for which treatment for the condition is indicated but is not controlled despite adequate therapy, including angina pectoris, cardiac arrhythmia, hypertension, congestive heart failure or myocardial infarction within the previous 26 weeks.

6. Other severe, acute, or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or study drug administration or that may interfere with the interpretation of study results and, in the judgment of the investigator, would make the patient inappropriate for the study.

7. Active, uncontrolled systemic infection considered opportunistic, life threatening, or clinically significant at the time of treatment.

8. Pregnant or lactating.

9. Known positive test result for hepatitis B surface antigen (HBsAg) or hepatitis C antibodies (HC Ab) or has a known positive test result for human immunodeficiency virus (HIV) or a history of HIV disease.

10. Serious medical or psychiatric condition that, in the opinion of the Investigator, should preclude the patient from participating in 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 nog niet gestart
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL6044
NTR-old	NTR6183
Ander register	2016-004595-22 : N16GEM

Resultaten

Samenvatting resultaten
None