PAREO study

Gepubliceerd: 13-04-2017 Laatst bijgewerkt: 13-12-2022

A decline of intra-tumoral concentrations over time could be the first sign of the development of drug resistance by the tumor. In this exploratory study we will investigate the relationship between plasma and intra-tumoral paclitaxel concentrations...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20604

Bron
NTR

Verkorte titel
PAREO

Aandoening

Oesophagus carcinoma, cancer, paclitaxel, intra-tumoral

Ondersteuning

Primaire sponsor: Erasmus University Medical Center
Overige ondersteuning: Erasmus University Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

a 25% reduction of the intra-tumoral concentrations of paclitaxel in cycle six compared to cycle one in oesophageal cancer patients.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a single centre pharmacokinetic study in which patients will use weekly paclitaxel 100mg/m2 and carboplatin on AUC 4 as standard of care chemotherapy. Patients will get on two different days (first day of the first and sixth cycle) 5x 4ml blood withdrawal for pharmacokinetic analysis, biopsies of the oesophageal cancer (4-8x (6mm (mean) diameter) tissue samples) and normal appearing mucosa (4-8x (6mm (mean) diameter) tissue samples).To demonstrate a 25% reduction of the intra-tumoral concentrations of paclitaxel in cycle six compared to cycle one in oesophageal cancer patients. Secondary endpoints include the relationship of the intra-tumoral concentrations of paclitaxel with pharmacokinetic paclitaxel parameters in plasma (i.e. AUC, CL, Cmax and tmax) per cycle, paclitaxel concentrations in tumor tissue compared to normal appearing mucosa, the analysis and correlation of toxicity and tumor response to intra-tumoral paclitaxel concentrations.

Doel van het onderzoek

A decline of intra-tumoral concentrations over time could be the first sign of the development of drug resistance by the tumor. In this exploratory study we will investigate the relationship between plasma and intra-tumoral paclitaxel concentrations over time.

Onderzoeksopzet

During cycle 1 and 6 patients will get an upper endoscopy with biopsies and blood withdrawal for pharmacokinetics.

Onderzoeksproduct en/of interventie

Patients will use weekly paclitaxel 100mg/m2 and carboplatin on AUC 4 as standard of care chemotherapy. Patients will get on two different days (first day of the first and sixth cycle) 5x 4ml blood withdrawal for pharmacokinetic analysis, biopsies of the oesophageal cancer (4-8x (6mm (mean) diameter) tissue samples) and normal appearing mucosa (4-8x (6mm (mean) diameter) tissue samples).

Contactpersonen

Publiek

Erasmus MC Cancer Institute - Department of Internal Oncology

F.M. de Man

‘s Gravendijkwal 230

Rotterdam 3015 CE
The Netherlands
Tel: +31 (0)10 7042451

Wetenschappelijk

Erasmus MC Cancer Institute - Department of Internal Oncology

F.M. de Man
‘s Gravendijkwal 230

Rotterdam 3015 CE
The Netherlands
Tel: +31 (0)10 7042451

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ¡Ý 18 years

- Oesophagus carcinoma

- WHO Performance Status 0-1

- Treatment with weekly paclitaxel 100mg/m2 and carboplatin on AUC 4 is indicated

- Written informed consent

- Patients with safely accessible tumor by upper endoscopy

- No concurrent medication or supplements which can interact with paclitaxel during the study period

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pregnant or lactating patients

- Previously treatment with radiotherapy on the oesophagus

- Patients who are unable to undergo upper endoscopy

- Patients with a stenosing oesophagus carcinoma

- Contra-indication for the use of midazolam and/or fentanyl (e.g. neuromuscular diseases, severe cardiac/pulmonary disease)

- Bilirubin > 1.5 x ULN, ASAT > 5x ULN, ALAT >5x ULN

- Serum creatinin > 2 x ULN and/or creatinin clearance < 45 mL/min (calculated with Cockroft-Gault formula)

- Patients with evidence or history of any bleeding diathesis, irrespective of severity

- Symptomatic CNS metastases or history of psychiatric disorder that would prohibit the understanding and giving of informed consent.

- Serious illness or medical unstable condition prohibiting adequate treatment and follow-up.

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 gestart
(Verwachte) startdatum:	13-03-2017
Aantal proefpersonen:	14
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-04-2017
Soort:	Eerste indiening

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	NL5990
NTR-old	NTR6356
Ander register	METC / ABR-nr : MEC16-696 / NL59789.078.16

Resultaten