

The influence of hyperhydration on pemetrexed concentrations in blood.

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Hyperhydration may cause augmented clearance of pemetrexed

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21433

Bron

Nationaal Trial Register

Verkorte titel

HYDRA

Aandoening

non-small cell lung cancer, NSCLC, mesothelioma

Ondersteuning

Primaire sponsor: ZANOB pharmacy/Jeroen Bosch Hospital

Overige ondersteuning: Self-financing research from ZANOB

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is the observed difference in the pharmacokinetics of pemetrexed when administered with or without hyperhydration.

Toelichting onderzoek

Achtergrond van het onderzoek

Pemetrexed is a pharmacotherapeutic cornerstone for treatment of non-small cell lung cancer and mesothelioma. Besides dose, renal function is the only determinant for systemic exposure: with decreasing renal function, systemic exposure increases accordingly. Since systemic exposure to pemetrexed (area under the concentration versus time curve (AUC)) is closely related with both efficacy measures (time to progressive disease) as (severe) toxicity, individualized dosing is of utmost importance to balance the dual risk of inefficacy and toxicity associated with treatment. We hypothesize that hyperhydration, which is given to promote excretion of cisplatin that is co-administered the first four cycles during combination therapy, causes augmented clearance of pemetrexed, resulting in decreased pemetrexed exposure. On the contrary, when in subsequent cycles cisplatin is not administered and hyperhydration is not performed, higher exposure and increased toxicity may be observed. Testing this hypothesis will further elucidate the pharmacokinetics of pemetrexed and may provide new insights regarding renal function as a determinant for optimal pemetrexed dosing and may be a next step to improved dosing with this cytotoxic agent.

Doel van het onderzoek

Hyperhydration may cause augmented clearance of pemetrexed

Onderzoeksopzet

To obtain pharmacokinetic parameters and renal function parameters blood samples are drawn at set times during one cycle of combination therapy with hyperhydration and one cycle of monotherapy. To determine if there is a possible time- or sequence effect, five patients will be sampled at an extra cycle of monotherapy.

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. At least 18 years old
2. Planned for treatment with cisplatin/pemetrexed combination therapy followed by pemetrexed maintenance therapy as a part of routine care.
3. Creatinine clearance $\geq$ 45ml/min
4. Subject is able and willing to sign the Informed Consent Form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients that suffer from conditions that affect hemostasis in a way that blood drawing is complicated

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-03-2018
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	06-03-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44619
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6889
NTR-old	NTR7076
CCMO	NL62137.028.17
OMON	NL-OMON44619

Resultaten