Increasing the amount of pazopanib in the blood by splitting intake moments

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The aim of this study is to show whether switching patients from a once daily (QD) to a twice daily (BID) dosing schedule will lead to a significant increase in pharmacokinetic exposure, measured as Cmin and AUC0-24h.

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

Samenvatting

ID

NL-OMON27697

Bron
NTR

Verkorte titel
N17PSI (pazopanib split intake)

Aandoening

Patients for who treatment with pazopanib is considered standard care (renal cell carcinoma and soft-tissue sarcoma).

Ondersteuning

Primaire sponsor: The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital
Overige ondersteuning: The Netherlands Cancer Institute - Antoni van Leeuwenhoek Hospital

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of the trial is to show whether switching patients from a once daily (QD) to a twice daily (BID) dosing schedule will lead to a significant increase in pharmacokinetic exposure, measured as Cmin and AUC0-24h.

Toelichting onderzoek

Achtergrond van het onderzoek

In the N17PSI we will study whether switching patients from pazopanib 800 mg QD to 400mg BID will increase the Cmin and AUC. This is relevant, because at the current dose of 800 mg QD approximately 20.0 - 57% of patients do not reach the pharmacokinetic target of Cmin > 20 mg/L.

Doel van het onderzoek

The aim of this study is to show whether switching patients from a once daily (QD) to a twice daily (BID) dosing schedule will lead to a significant increase in pharmacokinetic exposure, measured as Cmin and AUC0-24h.

Onderzoeksopzet

NA

Onderzoeksproduct en/of interventie

The intervention of the study consists of splitting the intake moments of pazopanib for one week into 400 mg BID instead of 800 mg QD.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Histological or cytological proof of cancer for which pazopanib is considered standard care;

2. Patients should have received pazopanib 800 mg QD as routine care

for at least 3 weeks before day 1 of the trial;

3. Age 18 years or older;

4. Able and willing to give written informed consent;

5. WHO performance status of 0, 1 or 2;

6. Adequate organ function as per judgement of the treating physician;

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Concomitant use of medication(s) which could influence the pharmacokinetics of pazopanib, consisting of (but not limited to) gastric acid suppressing agents, CYP3A4-inhibitors/inductors, PgP and/or BCRP modulators. In particular, proton pump inhibitors (such as omeprazole
and pantoprazole) are to be avoided;

2. Woman who are pregnant or breast feeding;

3. Patients with known alcoholism, drug addiction and/or psychiatric of physiological condition which in the opinion of the investigator wouldimpair study compliance;

4. Pazopanib related side effects that would require a dose reduction per judgement of the treating physician;

5. Legal incapacity;

6. (Calculated) pazopanib Cmin > 33 mg/L at screening visit.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2017
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	NL6137
NTR-old	NTR6275
Ander register	2016-005252-21 (EudraCT) : N17PSI (NKI-AVL study code)

Resultaten

Samenvatting resultaten
NA