Bioavailability of oral ciprofloxacin tablets versus suspension in pediatric cancer patients

Gepubliceerd: 26-06-2013 Laatst bijgewerkt: 18-08-2022

Whether the bioavailability of ciprofloxacin oral suspension and tablets are equivalent and can therefore be used interchangeably.

Ethische beoordeling	Niet van toepassing
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24417

Bron
NTR

Verkorte titel
BioCip

Aandoening

Cancer
Antimicrobial prophylaxis
Bioequivalence
Ciprofloxacin

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: KiKa, Go4Children

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The parameters to determine the bioequivalence are Area Under the Curve (AUC), maximum concentration (Cmax), time of maximum concentration (Tmax) and bioavailability (F). 6 blood samples (>= 0,5 ml each) for the different formulations will be drawn from the available central line; one trough level and five additional samples after administration of ciprofloxacin. These will used to calculate the pharmacokinetic parameters utilizing NONMEM (non-linear mixed effects modeling). These parameters of the formulations of ciprofloxacin will be compared to each other within the same patient. All samples and therefore pk parameters will be determined during steady state.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Ciprofloxacin is an antibiotic drug which is routinely used as anti-microbial prophylaxis during the treatment of pediatric cancer patients. Both tablets and oral suspension are used interchangeably without altering the dose. However bioavailability and therefore exposure might differ between these formulations.

Objective: To determine the relative bioavailability of ciprofloxacin oral suspension versus oral tablets in pediatric cancer patients, and to determine the absolute bioavailability of tablets and suspension utilizing the 100% bioavailability of intravenous administration. This will enable correct dose adjustments when switching between the different formulations.

Study design: This is an open label randomized cross-over pharmacokinetic study in children using ciprofloxacin according to standard treatment guidelines.

Study population: 15 pediatric cancer patients in the range of 1-19 years, who are treated with ciprofloxacin prophylaxis as part of standard treatment.

Intervention: Patients receiving ciprofloxacin for antibiotic prophylaxis during chemotherapy treatment according to standard supportive care guidelines will be randomized to receive either ciprofloxacin tablets or oral suspension (50 mg/ml) for 7 consecutive days, and

subsequently switch to the other formulation for the following 7 days, without a washout period in between. One random oral dose will be replaced by an intravenous dose of ciprofloxacin to determine the absolute bioavailability. During this period, blood samples will be drawn from the available Portacath catheter.

Main study parameters/endpoints: Determination of bioavailability (F), and related parameters: Tmax,ss, Cmax,ss, AUC.

*NTR4047 ended because of too low number of inclusions (=2).

Doel van het onderzoek

Whether the bioavailability of ciprofloxacin oral suspension and tablets are equivalent and can therefore be used interchangeably.

Onderzoeksopzet

Three sampling days (one for each formulation).

Sampling day: trough level, ciprofloxacin intake, 0,5h, 1h, 1,5h, 2h, and 6h.

Onderzoeksproduct en/of interventie

Patients are treated with ciprofloxacin as standard treatment. However for this study, ciprofloxacin will be relabeled as study medication for the duration of the study. The total treatment study period is 14 days; subjects will start with 7 days of oral solution and thereafter switched to 7 days of tablets or vice versa. Patients will be randomized to determine the starting formulation. During the treatment with each formulation 6 blood samples will be taken at least 48 hours after start of treatment (samples at steady state). In total 18 samples will be taken (6 per formulation).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥1 years and < 19 years;

- Patients treated with chemotherapy for pediatric cancer

- Patients who will receive ciprofloxacin treatment as antimicrobial prophylaxis according to standard supportive care guidelines

- Creatinine within normal limits according to age

- Possible to withhold antacids, sucralfate, iron, or other di/trivalent cations (e.g. zinc) for 6 h prior and 2 h after administration of ciprofloxacin on days of sampling (only one administration per day)

- Possible to withhold enteral feeding 4 h prior and 2 h after administration of ciprofloxacin on days of sampling (only one administration per day).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients unable/unwilling to take one of the ciprofloxacin formulations

- Patients with cystic fibrosis

- Patients with celiac disease

- Patients with abnormalities in the gastrointestinal tract, including severe chemotherapy induced mucositis/diarrhea

- Known or suspected malabsorption state

- Previous allergic reactions to fluorchinolones

- Hepatic insufficiency.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-08-2013
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL3886
NTR-old	NTR4047
Ander register	- : 2013-002744-89
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A