Revised dosing recommendations of ciprofloxacin for patients with impaired renal function: a bioequivalence study

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The rationale behind the guideline recommended dose reduction of ciprofloxacin in patients with impaired renal function is to achieve bioequivalence, defined as drug exposure equivalent to exposure in patients with adequate renal function receiving...

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

Samenvatting

ID

NL-OMON21894

Bron
NTR

Verkorte titel
Revised dosing recommendations of ciprofloxacin

Aandoening

(Bacterial) Infectious Diseases

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: Information will follow

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess bioequivalence of ciprofloxacin between patients with impaired renal function (eGFR 30 ml/min/1.73m2) receiving the revised reduced doses (test): 750 mg orally once daily or 600 mg intravenously once daily and patients with adequate renal function receiving regular doses (reference): 500mg orally twice daily or 400 mg intravenously twice daily by investigating whether drug exposure in the first 24 hours of treatment (AUC 0-24 is bioequivalent between both patient groups (test/reference).

Toelichting onderzoek

Achtergrond van het onderzoek

Objective: To compare exposure to ciprofloxacin between patients with impaired renal function (eGFR 30 ml/min/1.73m 2 receiving the revised reduced dose s test and patients with adequate renal function receiving regular doses reference by investigating whether exposure in the first 24 hours of treatment (AUC 0 24 is bioequivalent between both patient groups test/reference.

Doel van het onderzoek

The rationale behind the guideline recommended dose reduction of ciprofloxacin in patients with impaired renal function is to achieve bioequivalence, defined as drug exposure equivalent to exposure in patients with adequate renal function receiving a regular dose. However, results from a recent previous study by our research group showed that drug exposure is not equivalent, but statistically significant lower in patients with impaired renal function (eGFR 30 ml/min/1.73m2). Therefore we simulated on basis of a internally validated population pharmacokinetic model alternative dosing recommendations of ciprofloxacin for patients with impaired renal function. Results of these simulations show that a daily dose of ciprofloxacin of 750 mg orally and 600 mg in travenously (instead of the currently administered daily dose of 500 mg orally and 400 mg iv), should lead to equivalent drug exposure in patients with impaired renal function, defined by an estimated glomerular filtration rate (below 30 ml/min/1.73m2 (eGFR 30 ml/min/1.73m2) as in patients with adequate renal function receiving a regular dose.

Onderzoeksopzet

0-24 hours
24-48 hours

Onderzoeksproduct en/of interventie

1) Treatment with the revised reduced doses of ciprofloxacin for adult patients with impaired renal function. Patients with adequate renal function will be treated with the regular doses.
2) A maximum of four venapunctures in the first 48 hours of treatment with ciprofloxacin, obtaining a maximum of 16 ml blood in total.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- being treated with ciprofloxacin intravenously (or orally (as part of standard care
- age 18 years
- being admitted to general wards of the Ams terdam UMC location AMC or the OLVG location Oost
- informed consent is obtained

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- receiving renal replacement therapy i.e. haemodialysis, peritoneal dialysis, continuous venovenous hemofiltration or another way of renal replacement therapy), during the first 48 hours of treatment with ciprofloxacin
- patients with cystic fibrosis (CF)
- informed consent is not obtained

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	19-08-2020
Aantal proefpersonen:	46
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:	03-09-2020
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	NL8875
Ander register	METC AMC : 2020_005

Resultaten