Target attainment of ciprofloxacin in patients admitted to a general ward: a prospective observational study

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None, explorative study: explore whether the current dosing regimen of ciprofloxacin, recommended by the SWAB guidelines and applied at the Academic Medical Center for patients with various degrees of renal function admitted at general wards,...

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

Samenvatting

ID

NL-OMON25299

Bron
Nationaal Trial Register

Aandoening

Infections treated with ciprofloxacin, according to standard of care

Ondersteuning

Primaire sponsor: Academic Medical Center
Overige ondersteuning: Academic Medical Center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate whether the current dosing regimen of ciprofloxacin, recommended by the SWAB guidelines and applied at the Academic Medical Center for patients with various degrees of renal function admitted at general wards, results in the target PK/PD index of

AUC0-24/MIC ≥ 125.

Toelichting onderzoek

Achtergrond van het onderzoek

The target pharmacokinetic/pharmacodynamic (PK/PD) index of the antibiotic ciprofloxacin is the Area Under the plasma concentration-time Curve (AUC) over the minimum inhibitory concentration (MIC), with target AUC in 24 hours (AUC0-24) / MIC values greater than 125. With this study, we aim to investigate whether the current dosing regimen of ciprofloxacin, recommended by the Dutch ‘Stichting Werkgroep Antibioticabeleid’ (SWAB) and applied at the Academic Medical Center for patients with various degrees of renal function admitted at general wards, results in the target PK/PD index of AUC0-24/MIC ≥ 125.

Doel van het onderzoek

None, explorative study: explore whether the current dosing regimen of ciprofloxacin, recommended by the SWAB guidelines and applied at the Academic Medical Center for patients with various degrees of renal function admitted at general wards, results in the target PK/PD index of AUC0-24/MIC ¡Ý 125.

Onderzoeksopzet

For this observational study, three blood samples will be obtained from patients treated with ciprofloxacin according to standard of care, within the first 48hours of treatment.

Onderzoeksproduct en/of interventie

none.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Receiving ciprofloxacin therapy intravenous (iv) or per os (po) as part of standard care

- Age ¡Ý 18 years

- Admitted to general ward of the AMC

- Informed consent is obtained

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Incapacitated patients, i.e. a minor or legally incompetent adult

- Treatment with ciprofloxacin is started elsewhere

- Hemodialysis or peritoneal dialysis during treatment with ciprofloxacin

- Ciprofloxacin administered as prophylactic treatment and not as a treatment of a (suspected) infection

- Patients admitted to the intensive care unit (ICU)

- Severely burned patients, defined as a burned surface ¡Ý 10%

- Persons who cannot speak and read the English or Dutch language

- Informed consent is not obtained

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-01-2018
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44298
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6653
NTR-old	NTR6887
CCMO	NL63263.018.17
OMON	NL-OMON44298

Resultaten