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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25299

Source
Nationaal Trial Register

Health condition

Infections treated with ciprofloxacin, according to standard of care

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Academic Medical Center

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. 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 the peak concentration (Cmax) over the minimum inhibitory concentration (MIC) ≥ 8.

2. 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 for the ciprofloxacin unbound ciprofloxacin concentration of fAUC0-24/MIC ≥ 90.

3. If a large proportion, defined as a percentage of 25% or a minimum of 10 patients does not reach the PK/PD target of AUC0-24/MIC ≥ 125, our secondary aim is to determine whether an AUC0-24/MIC < 125 affects the patients' clinical outcome relative to patients who did reach the target in terms of:

- Days of fever, defined as a temperature ≥ 38.5°C, after start of treatment with ciprofloxacin, iv or po

- The percentage decrease of leucocyte count and CRP before and after 48-72 hours of treatment with ciprofloxacin

- Length of hospital stay in days after start of treatment with ciprofloxacin

- Switching ciprofloxacin to a more broad-spectrum antibiotic within 48 hours after start of treatment with ciprofloxacin

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

none.

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-01-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion
Date: 14-11-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44298
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results