Target attainment of ciprofloxacin as infection prophylaxis during chemotherapy-induced neutropenia in patients treated for haematological malignancies.

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Prospectively investigate whether ciprofloxacin, administered as antibiotic prophylaxis in patients treated for haematological malignancies (with or without gastro-intestinal mucositis), in the currently recommended dosing regimen (500 mg orally or...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Observational invasive

Summary

ID

NL-OMON48253

Source
ToetsingOnline

Brief title
Target attainment of ciprofloxacin as infection prophylaxis.

Condition

- Leukaemias
- Bacterial infectious disorders

Synonym
haematological malignancies, Infections

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ciprofloxacin, Haematology, Prophylaxis, Target attainment

Outcome measures

Primary outcome

PK/PD target attainment defined as AUC0-24/MIC * 125.

Secondary outcome

PK/PD target attainment defined as peak concentration (Cmax)/MIC * 8.

PK/PD target attainment defined as the unbound ciprofloxacin concentration

(fAUC0-24)/MIC * 90.

To analyze the amount of positive cultures with ciprofloxacin-resistant

bacteria or extended-spectrum *-lactamases (ESBL)-producing Gram-negative

bacteria in patients treated for haematological malignancies, who received

ciprofloxacin as infection prophylaxis.

Study description

Background summary

To prevent infections caused by commensal bacteria of the intestinal tract in patients treated for haematological malignancies, during profound and protracted neutropenia, ciprofloxacin as antibiotic prophylaxis is recommended. Although pharmacokinetics of antibiotics are likely to be changed by altered drug absorption due to adverse effects of cytostatic agents, like mucositis, diarrhea and vomiting and changes in distribution, metabolism and excretion, pharmacokinetic(PK) / pharmacodynamic(PD) target attainment has never been investigated. Underdosing of ciprofloxacin could threaten these patients, leading to suboptimal antibiotic prophylaxis, with negative effects on

patient*s outcome. Analyzing PK/PD target attainment is an accepted strategy to investigate the efficacy of the used dosing regimen.

Study objective

Prospectively investigate whether ciprofloxacin, administered as antibiotic prophylaxis in patients treated for haematological malignancies (with or without gastro-intestinal mucositis), in the currently recommended dosing regimen (500 mg orally or 400 mg intravenously twice a day or another dose, which is adjusted to renal function), results in the PK/PD target attainment of AUC0-24/MIC * 125.

Study design

Prospective, observational, single-center cohort study.

Study burden and risks

Risks imposed by participation are considered negligible.
By using population pharmacokinetic (PK) modeling, individual relevant pharmacokinetic parameters can be assessed on the basis of only 4 blood samples per patient. As a result, the participation burden and risk for the individual patient is low. Participation itself does not bring any benefit, but the group related benefit could be significant, based on substantial morbidity and mortality associated with bacterial infections in this vulnerable patient population, that could be prevented by efficient ciprofloxacin prophylaxis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Receiving ciprofloxacin orally or intravenously as prophylaxis as part of standard care prescribed by the treating physician
Admitted to the nursing ward of the haematology department or to another general ward, but treated for a haematological malignancy
Age * 18 years
Informed consent is obtained

Exclusion criteria

Admitted to the Intensive Care Unit
Receiving RRT (i.e. haemodialysis, peritoneal dialysis, continuous venovenous hemofiltration or another ways of RRT) during ciprofloxacin prophylaxis
Patients with cystic fibrosis
Severely burned patients, defined as a burned surface * 10%
Incapacitated patients, i.e. a minor or legally incompetent adult
Informed consent is not obtained

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2019
Enrollment:	46
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL67783.018.18