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

No registrations found.

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

Summary

ID

NL-OMON20490

Source
Nationaal Trial Register

Brief title
TBA

Health condition

All patients receiving ciprofloxacin prophylaxis as standard care will be included, regardless of treatment with different cytostatic agents, regardless of the severity of adverse effects of the treatment (in particular mucositis) and regardless of the degree and duration of neutropenia, as long as ciprofloxacin is recommended as infection prophylaxis within the applied treatment protocol.

Sponsors and support

Primary sponsor: Amsterdam UMC - location Academic Medical Centre (AMC), University of Amsterdam
Source(s) of monetary or material Support: Amsterdam UMC - location Academic Medical Centre (AMC), University of Amsterdam

Intervention

Outcome measures

Primary outcome

AUC0-24/MIC≥ 125, in which all relevant commensal Gram-negative bacteria of the intestinal tract will be taken into account.

Secondary outcome

Cmax/MIC ≥ 8, and fAUC0-24/MIC ≥ 90 based on an average unbound fraction of ciprofloxacin of 70% and analyze the frequency of positive cultures with ciprofloxacin-resistant organisms or ESBL-producing Gram-negative bacteria in patients treated for haematological malignancies.

Study description

Background summary

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

Study objective

Exploratory study investigating the efficacy of the currently recommended dosing regimen of ciprofloxacin prophylaxis in patients treated for haematological malignancies.

Study design

Four venapunctures in a time period of 48 hours and one questionnaire about the frequency and consistency of the stools.

Intervention

No intervention in patient’s ‘treatment’ is made, intervention consists of four venapunctures in a time period of 48 hours, obtaining a maximum of 12 ml of blood in total and one questionnaire about the frequency and consistency of the stools.

Contacts

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Eligibility criteria

Inclusion criteria

Hospitalized adult patients (age ≥ 18 years) receiving ciprofloxacin as infection prophylaxis as part of standard care prescribed by the treating physician.

Exclusion criteria

Four patient-groups will be excluded as they are known to exhibit altered pharmacokinetics of antibiotics: patients in the intensive care unit (ICU), all patients receiving renal replacement therapy (RRT), patients with cystic fibrosis (CF) and severely burned patients.

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:	Recruiting
Start date (anticipated):	12-02-2019
Enrollment:	46
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	12-02-2019
Application type:	First submission

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
NTR-new	NL7520
Other	METC AMC : METC 2018_290

Study results