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

Gepubliceerd: 12-02-2019 Laatst bijgewerkt: 13-12-2022

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

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

Samenvatting

ID

NL-OMON20490

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

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.

Ondersteuning

Primaire sponsor: Amsterdam UMC - location Academic Medical Centre (AMC), University of Amsterdam
Overige ondersteuning: Amsterdam UMC - location Academic Medical Centre (AMC),

University of Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

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 gestart
(Verwachte) startdatum:	12-02-2019
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:	12-02-2019
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	NL7520
Ander register	METC AMC : METC 2018_290

Resultaten