Dose individualization of Beta-lactam and fluoroquinolone antibiotics in ICU patients: to TDM or not to TDM and the effects on Outcome

Gepubliceerd: 18-05-2018 Laatst bijgewerkt: 13-12-2022

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21680

Bron
NTR

Verkorte titel
DIABOLO

Aandoening

Intensive care, Antibiotics, Pharmacodynamics, Pharmacokinetics

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pharmacodynamic target attainment:

- Beta-lactam: %ƒT>MIC(ECOFF) (including % of patients with 100%ƒT>MIC(ECOFF) in both groups).
- Fluoroquinolone: ƒAUC/MIC(ECOFF) (including % of patients with ƒAUC/MIC(ECOFF)≥100 in both groups)

Toelichting onderzoek

Achtergrond van het onderzoek

Traditional antibiotic dosing is not designed for ICU patients. An 'one-dose-fits-all' approach is therefore likely to be inadequate, because the extreme pharmacokinetic behaviour of drugs in critically ill threatens the achievement of optimal antibiotic treatment. Moreover, ICU patients are at risk of developing infections with resistant micro-organisms, due to density of vulnerable patients and complexity of care. The aim of this trial is to evaluate a new early dosage adjustment strategy (TDM) of beta-lactam and fluoroquinolones in adult ICU patients to achieve the adequate pharmacodynamic targets (PDT), compared to the usual treatment strategy. Secondary aims are clinical outcome, the impact on antimicrobial resistance, and cost-effectiveness analyses between the TDM and non-TDM group.

Onderzoeksopzet

- For each patient 2 separate blood samples are collected within 12-24 hours after first dose, to evaluate this new early dosage adjustment strategy. The first sample is taken at 50% of the dosing interval and the second (trough) 5-10 min prior to the next dose. Follow-up levels will be collected on day 2 (T=36-48h) after the initial first dose (after at least 2-4 subsequent doses of the newly adapted dosing regimen in the intervention group), and thereafter on day 5.

- Time Frame clinical data collection: 30d after inclusion

Onderzoeksproduct en/of interventie

Assigned interventions in the active TDM group: dosage of beta-lactam and fluoroquinolone antibiotics will be adjusted according to serum concentrations. In the non-TDM (control) group samples of serum concentrations of beta-lactam and fluoroquinolone will be collected for comparison.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ≥18 years of age

- Receiving intravenous antibiotic therapy of the target drugs

- Treatment should be aimed for at least 2 days.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Pregnancy

- Patient already enrolled in this trial

- Antibiotic cessation before sampling

- Medium care and burn wound patients admitted to the ICU

- Patients receiving cefotaxime as prophylaxis only within the context of Selective Digestive tract Decontamination (SDD)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	18-05-2018
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	NL7018
NTR-old	NTR7216
Ander register	: MEC-2017-568

Resultaten