

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 Laatste bijgewerkt: 13-12-2022

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

Samenvatting

ID

NL-OMON21680

Bron

Nationaal Trial Register

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: %fT>MIC(ECOFF) (including % of patients with 100%fT>MIC(ECOFF) in both groups).
- Fluoroquinolone: fAUC/MIC(ECOFF) (including % of patients with fAUC/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

Publiek

Erasmus Medical Centre - Department of Hospital Pharmacy

A Abdulla
's Gravendijkwal 230

Rotterdam 3015 CE
The Netherlands
+31(0)10-7040704/+31(0)6-42119481

Wetenschappelijk

Erasmus Medical Centre - Department of Hospital Pharmacy

A Abdulla
's Gravendijkwal 230

Rotterdam 3015 CE
The Netherlands
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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
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

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

NTR-new

NTR-old

Ander register

ID

NL7018

NTR7216

: MEC-2017-568

Resultaten