An exploratory pharmacokinetics and pharmacodynamics study beta-lactam antibiotics in pediatric intensive care patients: is there a need for more precision?

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29496

Source
Nationaal Trial Register

Brief title
EXPAT Kids

Health condition

Infectious diseases

Sponsors and support

Primary sponsor: MRace
Source(s) of monetary or material Support: MRace

Intervention

Outcome measures

Primary outcome

The main objective is to determine the prevalence of target attainment for six frequently used beta-lactam antibiotics in the early phase after start of the therapy in PICU patients. Target attainment for beta-lactam antibiotics is set at 100% of time (T) of the dosing interval in which the unbound (free, ƒ) serum antibiotic concentration remains above the above the epidemiological cut-off (ƒT > MICECOFF).

Secondary outcome

To identify risk factors and clinical outcomes associated with target non-attainment. Factors likely to contribute to outcomes are analysed for association based on clinical relevancy and previously described relationship, and include:
• Length of PICU stay, days on antibiotics, microbiological cure, and other clinical outcomes in PICU patients
• Use of other antibiotics
• C-reactive protein (CRP), interleukin 6 (IL-6), and procalcitonin
• Antibiotic resistance development
• Serum albumin
• Estimated glomerular filtration rate (eGFR ≥ 90 mL/min/1.73 m2)
• Presence of continuous renal replacement therapy (CRRT)

Study description

Background summary

Morbidity and mortality in critically ill patients with infection is a global health problem. Emerging evidence supports the importance of optimized antibiotic exposure in pediatric intensive care unit (PICU) patients, while evidence based antibiotic dosing in PICU patients in clinical practice is limited. Changes in pharmacokinetic (PK) parameters of antibiotics in subpopulations of critically ill patient have been defined in previous studies. However, there are no data from studies assessing whether the issues identified in a controlled research environment correspond to clinical practice. Assessment of pharmacodynamic target attainment is warranted to identify whether clinical outcomes for patients admitted to the PICU can be improved. We propose an exploratory pharmacokinetic and pharmacodynamic (PK/PD) study to analyse whether current antibiotic dosing regimens of frequently used beta lactam antibiotics achieve defined therapeutic target concentrations in PICU patients.

Study objective

Current antibiotic treatment with beta lactam do not meet pharmacodynamic targets in pediatric intensive care unit patients

Study design

Day 0 till 6: bioanalysis of bloodsamples for drug exposure (primary)

Week 1: data abstraction EPR (secondary)

Contacts

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Eligibility criteria

Inclusion criteria

• Written informed consent has been obtained from the patient or their legally authorised representative
• Suitable intra-arterial access to facilitate sample collection
• Recruitment within 36 hours after start of antibiotic therapy
• Intravenous antibiotic therapy of the target antibiotic should be aimed for at least 2 days

Exclusion criteria

• Consent not obtained
• Premature infants
• History of anaphylaxis for the study antibiotics
• Study antibiotic cessation before blood collection
• Prophylactic use of the study antibiotics

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-05-2021
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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	NL9326
Other	METC EMC : MEC-2021-0173

Study results