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21. S - CLINICAL USE OF ANTIMICROBIALS FOR TREATMENT

ANTIBIOTICS IN NEONATAL SEPSIS: CURRENT USES AND FUTURE TRENDS (on behalf of TEDDY Network)

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Background and Objective

Up to 90% neonates are exposed to at least one antibiotic during their stay in NICUs. Drugs tailored for neonates are needed. With reference to medicines currently used for neonatal sepsis, we report the MA status and the existing/ongoing studies supporting their use.

Methods

Guidelines and scientific publications were used as sources to identify antibiotics for neonatal sepsis treatment. TEDDY European Paediatric Medicines Database provided information on the EMA and nationally approved drugs (in UK and Italy). Completed and ongoing clinical studies were searched consulting EPARs and clinical trial registries (www.clinicaltrial.gov, www.clinicaltrialsregister.eu). Additionally, we searched Head of Agencies (HMA) database.

Learning Points Discussion

Our data demonstrate that

- none of the antibiotic approved by the EMA is indicated for neonatal sepsis;
- 3/40 antibiotics currently used in NICUs are licensed for neonatal sepsis, 4 are approved for neonatal indications but sepsis is not specified, 5 include a dosage without a neonatal indication; Benzyl penicillin is licensed for prevention but not for treatment, while Cefuroxime is licensed for neonatal infections but not for neonatal sepsis;
- of the 3 approved drugs, only gentamicin has paediatric clinical pharmacology; the 5 drugs for which a dosage is indicated do not have any PK study;
- a total of 12 neonatal studies are reported in the HMA database, 5 are PK and 3 comparative (of the 22 studies in the clinical trial databases, 11 are interventional and 1 observational), globally including more than 5500 newborns. No study includes a novel molecule.

All the antibiotics used in NICUs for neonatal sepsis are off-patent and the majority is used 'off-label'. The most intensive studied drug is gentamicin in association with other antibiotics, while meropenem is the most studied antibiotic as single therapy (as detailed in tables).
