KCE-181128 – Beneficial

A multicentric, individually randomised, controlled clinical study into the impact of a computer program for precision dosing of vancomycin in critically ill children

Why this study?

Vancomycin is an **antibiotic** with a **narrow therapeutic-toxic margin**. This means that the minimum and maximum required target concentrations in the blood differ only slightly. Too low concentrations result in a reduced effect of the antibiotic. Higher concentrations often cause serious side effects, including renal toxicity. Adjusting the **dose of vancomycin** for the sick child is therefore a huge challenge.

Currently the dose of vancomycin for all patients is calculated at the start of therapy based on milligram per kilogram. The dose is then adjusted according to a too high or too low dose of the concentration of vancomycin measured in the blood. Despite this measurement, it is still a major challenge to achieve the required target concentration (quickly).

In this study we investigate the **added value of a user-friendly computer program** that calculates the dose of vancomycin for critically ill children. We specifically study whether the computer program results in a faster calculation of the target concentrations, less frequent and less serious side effects on the kidney, less stress for the patient, a faster recovery and a shorter stay in hospital.

Summary of the study

This project is financed by the Belgian Health Care Knowledge Centre (KCE). **390 critically ill children between the age of 0 and 18** will be included on the departments neonatology, intensive care paediatrics and paediatric haematology/oncology of 7 Belgian hospitals.

The on-site and remote monitoring will be carried out in accordance with ICH-GCP by the Health, innovation and research institute of Ghent University Hospital.

This study was approved by the Committee for Medical Ethics of Ghent University Hospital following consultation with the ethical committees of each Belgian centre where the study will be carried out.

Study protocol and documents

The research team, the study protocol and other useful study documents can be consulted via this secure webshare . You will need a password to do this. For this please contact project manager Anca Amza: anca.amza@uzgent.be.

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