

Prospective multicentre randomised, double-blind, equivalence study comparing clonidine and midazolam as intravenous sedative agents in critically ill children: the SLEEPS (Safety profile, Efficacy and Equivalence in Paediatric intensive care Sedation) study

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Plain English summary

The SLEEPS study

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Plain English summary

In the Safety profile, Efficacy and Equivalence in Paediatric intensive care Sedation (SLEEPS) study we compared how well two different sedative medicines worked (clonidine and midazolam) in children.

A total of 129 patients took part in the study. We wanted to know which medicine performed best in keeping the children adequately sedated for at least 80% of the time (when used alongside morphine). There were a number of challenges in the study, which meant that fewer children than planned completed the trial.

The results showed that midazolam and clonidine were very similar in how well they kept children sedated. We found that the children on midazolam were sedated for longer than those on clonidine. We also found that those children on midazolam woke up more quickly, despite being on the medicine for a longer period. When children are taken off sedative medicine they may have withdrawal symptoms. In this study we found that more children in the midazolam group needed treatment for withdrawal. We also found that when the sedative was first started and stopped, some of the children who were given clonidine experienced changes in their blood pressure and heart rate.

A key finding is that neither drug provides ideal sedation. Further work is urgently needed to find better techniques to adequately sedate children. Fewer children took part in this study than we had hoped, and this has some limitation on our conclusions.

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