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Synopsis

Melatonin versus midazolam in the premedication of anxious children attending for elective surgery under general anaesthesia: the MAGIC non-inferiority RCT

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Published July 2025
DOI: 10.3310/CWKF1987
Volume 29 • Issue 29

Plain language summary

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Health Technology Assessment 2025; Vol. 29: No. 29
DOI: 10.3310/CWKF1987

NIHR Journals Library www.journalslibrary.nihr.ac.uk

This synopsis should be referenced as follows:
Deery C, Bolt R, Papaioannou D, Wilson M, Hyslop M, Herbert E, *et al*. Melatonin versus midazolam in the premedication of anxious children attending for elective surgery under general anaesthesia: the MAGIC non-inferiority RCT. *Health Technol Assess* 2025;**29**(29). https://doi.org/10.3310/CWKF1987

Plain language summary

Why did we do this trial?

The hospital anaesthetic room can be a worrying place for a child. Reducing a child's distress can lead to better outcomes, including improved recovery from general anaesthesia, avoidance of delays or rescheduling of surgery and reduction in pain. Children with high levels of anxiety are given a calming medicine or 'premedication' prior to their general anaesthesia. In the United Kingdom, the most used medicine is 'midazolam', which is effective, but has side effects including breathing problems, feeling wobbly and unpredictable reduction in anxiety. Another calming medicine, 'melatonin', has shown promise, as it avoids midazolam's side effects. It is a natural hormone produced in the human body, which causes sleepiness. The trial compared melatonin with midazolam in anxious children undergoing general anaesthesia for routine surgery across 20 United Kingdom hospitals.

What did we do?

Children who fitted the study criteria were consented and 'randomised' to receive midazolam or melatonin. Neither the children, their parents, nor their care staff knew which medicine they got. We looked at the level of the children's anxiety from the time of entering the hospital until being given the anaesthetic, to see if there was a difference between how good the two medicines were at calming, as well as comparing costs, side effects and other measurements. We followed up the children 2 weeks later and interviewed some hospital staff, parents and children about their views.

What did we find?

The trial was stopped early as it could not recruit enough participants. As with many studies, the COVID pandemic had a large impact on recruitment, and so the results of our study are not as definitive as we originally intended. However, we found that midazolam was better than melatonin at reducing anxiety in anxious children prior to their general anaesthesia. We also learnt what factors influence the choice of calming medicines and how we can better design future trials in similar groups. No significant differences in side effects were seen between the two medicines. There was uncertainty in the results of the cost-effectiveness analysis, though melatonin was found to be slightly cheaper (£46.20) than midazolam.

What does this mean?

While midazolam is more effective at calming children than melatonin, alternative medicines with fewer side effects need to be explored as premedications.