Pfizer Trial Supports Paxlovid Dose for High-Risk Children

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The management of COVID-19 in high-risk paediatric populations has presented a clinical challenge, particularly concerning the appropriate dosing and efficacy of antiviral treatments. While nirmatrelvir/ritonavir (Paxlovid) has demonstrated efficacy in adults1, data for children has been less extensive. A recent trial provides evidence supporting the use of Paxlovid in high-risk paediatric patients, suggesting that a dose based on adult data for similar risk profiles may be appropriate.

KEY TAKEAWAYS

- The Pivot: Data now supports Paxlovid dosing for high-risk children, aligning with adult regimens.
- The Data: The trial demonstrated a safety profile consistent with that observed in adults.
- The Action: Clinicians may consider Paxlovid for high-risk paediatric patients based on these findings, adhering to established risk stratification.

The emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) necessitated the rapid development of effective antiviral therapies. Nirmatrelvir, co-packaged with ritonavir (Paxlovid), received emergency use authorisation for the treatment of mild-to-moderate COVID-19 in adults and paediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19, including hospitalisation or death. This authorisation was primarily based on data derived from adult populations, specifically the EPIC-HR trial, which demonstrated a significant reduction in the risk of COVID-19-related hospitalisation or death from any cause by 89% (relative risk reduction) compared to placebo in non-hospitalised adults with mild-to-moderate COVID-19 who were at high risk for progression to severe disease.1

However, the specific dosing and safety profile of nirmatrelvir/ritonavir in younger paediatric populations, particularly those under 12 years of age or weighing less than 40 kg, remained an area requiring further investigation.

Children, especially those with underlying medical conditions such as chronic lung disease, congenital heart disease, immunosuppression, or obesity, are also at increased risk for severe COVID-19 outcomes. The absence of dedicated paediatric trial data for these younger, high-risk groups has meant that clinicians have had to extrapolate from adult data or rely on limited observational studies, posing a dilemma for evidence-based prescribing. This trial aimed to address this gap by evaluating the pharmacokinetics, safety, and efficacy of nirmatrelvir/ritonavir in high-risk paediatric patients, thereby providing a more robust evidence base for treatment decisions in this vulnerable population.

The trial

The trial was a multicentre, open-label, single-arm study designed to evaluate the pharmacokinetics, safety, and efficacy of nirmatrelvir/ritonavir in paediatric patients at high risk for progression to severe COVID-19. The study enrolled paediatric participants aged 6 to 103 paediatric patients across various sites.2

The pharmacokinetic analysis demonstrated that the selected paediatric doses of nirmatrelvir/ritonavir achieved plasma concentrations of nirmatrelvir that were consistent with those observed in adults who received the authorised 300 mg nirmatrelvir/100 mg ritonavir dose. This finding is critical as it suggests that the drug exposure in children is within the therapeutic range established in adult studies, thereby providing a pharmacological basis for efficacy. Specifically, the geometric mean ratio (GMR) for nirmatrelvir area under the curve (AUC) in paediatric patients compared to adults was 0.95 (90% confidence interval [CI]: 0.88, 1.03), indicating bioequivalence. The safety profile observed in the paediatric cohort was generally consistent with that reported in adults. The most common adverse events (AEs) were dysgeusia (15%), diarrhoea (10%), and vomiting (8%), which are known AEs associated with nirmatrelvir/ritonavir. Serious adverse events (SAEs) occurred in 2% of participants, none of which were considered related to the study drug. There were no deaths reported during the study period. Clinical outcomes, while not a primary endpoint for this pharmacokinetic and safety study, showed that 98% of participants experienced resolution of symptoms by Day 28, and no participants progressed to severe COVID-19 requiring hospitalisation or mechanical ventilation. These clinical observations, while exploratory, align with the expected efficacy profile of nirmatrelvir/ritonavir.2

The trial's findings provide important data to support the use of nirmatrelvir/ritonavir in high-risk paediatric patients. The pharmacokinetic data confirm that appropriate drug exposure can be achieved with weight-based or age-based dosing strategies, which is a fundamental requirement for extending treatment indications to younger populations. The safety profile, consistent with adult data, further supports the potential for clinical application. However, the study was open-label and single-arm, which inherently limits the ability to draw definitive conclusions regarding comparative efficacy against placebo or other treatments. The relatively small sample size, particularly within specific age and weight cohorts, also means that rare adverse events or subtle differences in efficacy might not have been detected. Future studies, potentially larger and placebo-controlled, would be beneficial to further solidify the efficacy data and to explore the long-term safety and effectiveness in a broader range of paediatric patients, including those with varying degrees of risk factors or different viral variants. Additionally, research into the optimal timing of administration and potential drug-drug interactions in paediatric patients remains an area for continued investigation.

CLINICAL IMPLICATIONS

The data from this trial offers a pragmatic step forward for clinicians managing high-risk paediatric patients with COVID-19. The demonstration of comparable pharmacokinetic profiles between children and adults, coupled with a consistent safety profile, provides a much-needed evidence base for prescribing nirmatrelvir/ritonavir in this vulnerable population. It suggests that the established adult dosing principles, adjusted for weight and age, are likely to translate effectively, reducing the reliance on anecdotal evidence or off-label prescribing.

For the pharmaceutical industry, particularly Pfizer, this trial reinforces the broader utility of Paxlovid and expands its potential market. The investment in paediatric trials, even single-arm ones, is critical for securing broader regulatory approvals and demonstrating a commitment to addressing unmet needs across age groups. This data will likely support updated prescribing information, providing greater clarity and confidence

> for healthcare providers and potentially increasing uptake in paediatric settings where the risk of severe COVID-19 remains a concern.
> Patients and their families stand to benefit from clearer guidance and a validated treatment option. The anxiety associated with severe COVID-19 in high-risk children can be substantial, and having an evidence-backed oral antiviral available for early intervention offers a significant advantage. While the trial was not placebo-controlled for efficacy, the pharmacokinetic and safety data provide a strong foundation for clinical decision-making, allowing for earlier and more confident intervention to potentially mitigate the progression to severe disease in those most susceptible.

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