

Can young children swallow multiple coated mini-tablets? Results from an open-label, single-dose crossover study

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Aims & Objectives: The development of child-appropriate drug formulations can be challenging. Mini-tablets are advantageous over liquid formulations in overcoming challenges related to stability, taste, and dosage. We investigated the acceptability of drug-free coated mini-tablets among children aged 1 month to 6 years and their preference for swallowing either smaller or larger mini-tablets for the respective age range based on body weight, thus guiding an optimal mini-tablet size selection for pediatric patients.

Methods: This open-label, single-dose study at the University Children's Hospital Düsseldorf randomized 320 children across five age groups (4 to 6 years, 2 to <4 years, 1 to <2 years, 6 to <12 months, and 1 to <6 months) to receive 2.0mm or 2.5mm mini-tablets in a crossover fashion (note, fewer 2.5mm mini-tablets were used). Recruitment in the 1 to <6-month age group was stopped early due to 'swallowing the wrong way/coughing' in 3 children. The primary objective was to assess acceptability derived from swallowability scoring ('Yes'=swallowability score 1/2; 'No'=swallowability score 3–5). Secondary objectives included investigator-observed palatability (rated as 'pleasant', 'neutral', or 'unpleasant'), acceptability as a composite endpoint of palatability and swallowability, and safety.

Results: In total, 319 children completed the study. Across all tablet sizes, quantities, and age groups, acceptability rates were high and comparable (averaged difference –0.3%, 90% CI: –2.0 to 1.4; p=0.757), palatability was rated as 'pleasant' for most children (averaged difference 1.0%, 90% CI: –0.2 to 2.2; p=0.178; 'neutral' rating in 1 to <6-month age group in line with developmental milestones), and the composite endpoint showed 'high' or 'good' acceptability (averaged difference –0.6%, 90% CI: –2.6 to 1.3; p=0.588). No adverse events or deaths were reported.

Conclusion: Children aged 6 months to 6 years showed acceptability and tolerability for both 2.0mm and 2.5mm mini-tablets. Coated mini-tablets are potentially suitable formulations for pediatric patients.

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