

Background

Postoperative Nausea and Vomiting (PONV) in Children

- Commonly assessed as postoperative vomiting (POV) in pediatric population
- Challenging due to complexities in evaluating nausea, particularly in younger individuals^{1,2}
- Higher incidence of PONV in children compared to adults^{2,3,4}
- The inadequate assessment of pediatric nausea may result in undertreatment^{2,5}
- Little guidance for clinicians on how to treat PONV in children due to limited outcomes data in pediatric PONV

Amisulpride

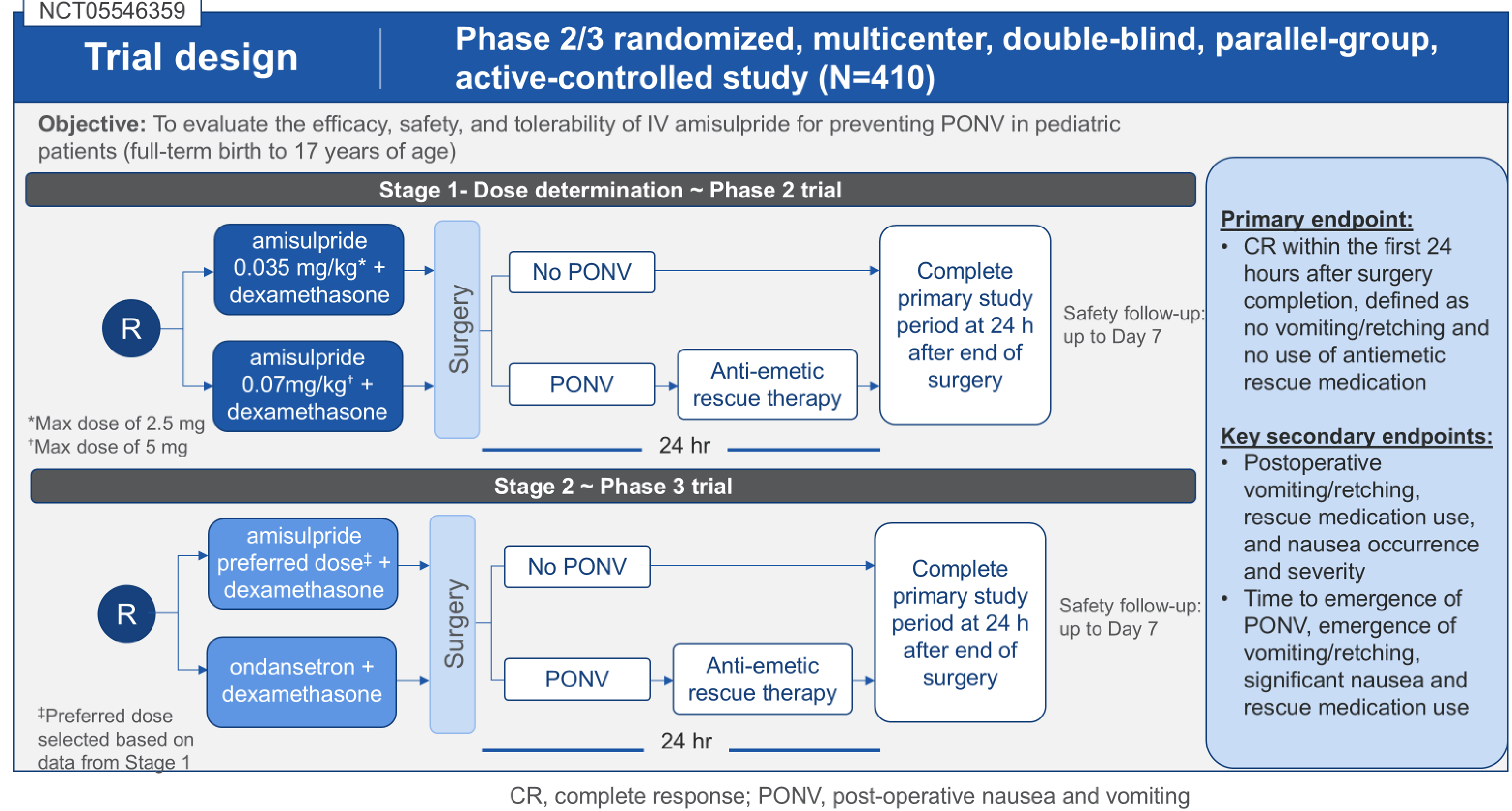
- Selective dopamine D₂ and D₃ receptor (D₂R, D₃R) antagonist⁶
- Only FDA approved antiemetic for PONV rescue treatment⁶
- FDA approved in adults in 2020⁶ for
 - Prevention of PONV, either alone⁷ or in combination with an antiemetic of a different class⁸
 - Treatment of PONV in patients who have received antiemetic prophylaxis with an agent of a different class⁹ or have not received prophylaxis¹⁰
- Exhibits substantial efficacy in reducing nausea⁷⁻¹⁰, positioning it as a promising candidate for managing pediatric PONV
- The evaluation of IV amisulpride in pediatric patients, mandated by the US Pediatric Research Equity Act, aligns with best practices for assessing potential benefits in this population

Study Objective

As part of the Food and Drug Administration (FDA) Pediatric Study Plan (PSP), this study aims to assess the efficacy and safety of IV amisulpride for the prevention of PONV in pediatric patients undergoing surgery.

Acknowledgements and Disclosures

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Results

- As of 25 October 2024, 177 patients have been screened in Stage 1 with 176 randomized
 - 99 patients in Cohort 1 (≥12 and <18 years); 77 patients in Cohort 2 (≥ 3 and <12 years)
 - 162 patients treated with amisulpride
 - One screen failure; nine withdrawn consent/early termination
- 50 plasma pharmacokinetic (PK) amisulpride samples have been drawn
 - 34 in Cohort 1 and 16 in Cohort 2
- Interim analysis of safety/efficacy and PK data will occur after 166 treated patients and statistical analyses of key efficacy measurements by Independent Data Monitoring Committee (IDMC) to determine appropriate dose to take forward to Stage 2 (amisulpride vs ondansetron active comparator)
- If PK samples are in line with predictions/modelling based on adult PK data, and safety data are acceptable, the youngest cohort will also be opened (full-term birth to <3 years)
- 95 total adverse events (76 mild/19 moderate/no severe AEs); 45 patients reported AEs
- No Serious Adverse Events (SAEs) reported
- Results are expected in the first half of 2025

Conclusions

- Amisulpride shows promise as a safe and effective agent for treating PONV in infants and children
- It is hoped that this trial will provide clarity for clinicians regarding reported disparities in the incidence and management of PONV, particularly nausea, in children as compared to adults
- Results from this trial will guide administration of future Phase 3 pediatric PONV trial in treatment, including rescue treatment, of children

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