

## Diazepam



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Research reports that diazepam is one of three benzodiazepines effective in treating children with status epilepticus (SE), a condition of prolonged or repeated seizures that affects 4 to 8 per 1,000 children before they are 15 years of age. However, dosing in children has largely been extrapolated from adults.

### Studies

**Pharmacokinetics of Diazepam in Children with SE (NICHD-2015-DZP01)** aimed to analyze how diazepam is metabolized by children with pediatric SE. The study used clinical data and pharmacokinetic (PK) samples from 158 children who were randomized to receive diazepam in a previous BPCA study (<https://dash.nichd.nih.gov/study/18573>). Among the 158 participants, 87 provided evaluable PK data. DZP01 developed a population PK model for diazepam in children with SE between age 3 months to 18 years of age. The study design also incorporated the effect of body size on drug distribution.

A clinical study report summarizing NICHD-2015-DZP01 was submitted to the U.S. Food and Drug Administration (FDA) for review and consideration of improved pediatric labeling.

### Findings

- Compared with existing FDA label dosing, the study dose (0.2 mg/kg IV, maximum 8 mg) resulted in greater frequency in achieving the target therapeutic range of 200-600 ng/mL ([PMID: 30267478](https://pubmed.ncbi.nlm.nih.gov/30267478/)).
- **Key Outcome:** The rapid onset of diazepam is important to control future seizure activity and reduce the risk of neurological damage. The dosing data from this study will provide additional information to clinicians on correct dosing based on weight when providing care to their patients. The optimal therapeutic dose of diazepam for children with status epilepticus has been found to be 0.2 mg/kg IV up to a maximum of 8 mg.

### Resources

- NICHD's [Data and Specimen Hub](https://dash.nichd.nih.gov/study/18570) provides an overview of the study population and, for registered users, free access to datasets, study reports and documentation.
  - <https://dash.nichd.nih.gov/study/18570>
- ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT00621478>
- FDA Label: <https://bit.ly/2WZTLBE> (FDA is reviewing BPCA study data for updates.)

**About BPCA:** The NICHD-led BPCA program at NIH helps advance pediatric drug research & development and improves information about and labeling for drugs used in children. The program identifies research gaps in pediatric therapeutics, prioritizes drugs in need of further study, supports research training, and sponsors clinical studies of prioritized drugs through the Pediatric Trials Network. Learn more at <https://www.nichd.nih.gov/BPCA>.



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