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Lithium has been used as a first- or second-line treatment of bipolar disorder, which is a significant mental health problem in children. However, better evidence was needed regarding the safety and effectiveness of lithium treatment in children. As a result of the following pediatric research, the U.S. Food and Drug Administration (FDA) updated the lithium label in 2018.

### Studies

**COLT1: Pediatric Pharmacokinetic (PK) and Tolerability Study of Lithium for the Treatment of Pediatric Mania Followed by an Open Label Long Term Safety Period, Discontinuation Phase, and Restabilization Period**, a multiphase study, included 61 children at seven U.S. medical centers.

**COLT2: A Randomized, Double-Blind, Placebo Controlled Study of the Efficacy of Lithium for the Treatment of Pediatric Mania Followed by an Open Label Long-Term Safety Period, Double-Blind, Placebo-Controlled Discontinuation Phase, and Open Label Restabilization Period (NICHD-2005-07-2)** was conducted at 11 U.S. medical centers, and enrolled 153 children in the screening phase. Of those, 81 were randomized into the efficacy phase.

### Findings

- PK, safety (tolerability), and long-term effectiveness data from these studies supported new dosing recommendations for children ([PMID: 18700004](#)).
- **Key Outcome:** Lithium is an effective and safe treatment of acute mania in children with bipolar disorder as well as the long-term management of the disorder. The U.S. Food and Drug Administration (FDA) updated the label in October 2018.

### Resources

- NICHD's [Data and Specimen Hub](#) provides an overview of the study population and, for registered users, free access to datasets, study reports and documentation.
  - COLT1: <https://dash.nichd.nih.gov/Study/16018>
  - COLT2: <https://dash.nichd.nih.gov/Study/16020>
- ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT01166425>
- FDA Label: <https://bit.ly/2yphaSD>

**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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