

Best Pharmaceuticals for Children Act (BPCA)

Acyclovir



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Acyclovir is used commonly to treat neonatal herpes simplex virus (HSV), which if untreated, carries a high risk of death among newborns. Treatment with acyclovir reduces this risk dramatically. As a result of the following pediatric research, the U.S. Food and Drug Administration (FDA) updated the acyclovir label in 2019.

Studies

ACY01: An Open Label Study to Describe the Pharmacokinetics of Acyclovir in Premature Infants (NICHD-2005-07-1) evaluated acyclovir treatment in critically ill preterm and term infants with suspected or confirmed HSV. ACY01 was conducted at two U.S. medical centers and enrolled 32 children.

ACY02: Safety and Efficacy of High-Dose Acyclovir in Infants with HSV or Suspected HSV (NICHD-2013-ACY02) was a retrospective review of data from three sources: 1) Data on 368 infants in U.S. neonatal intensive care units run by Pediatrix Medical Group; 2) Medical records of 49 infants treated at four academic health centers; 3) Two published clinical trials of acyclovir treatment for neonatal HSV, the first on high-dose intravenous acyclovir ([PMID: 11483782](#)), and the other comparing vidarabine with acyclovir ([PMID: 1988829](#)).

Findings

- ACY01 found that dosing for neonatal HSV treatment should be based on postmenstrual age and that optimal doses were higher than those included in the acyclovir label at the time of the study ([PMID: 24346595](#)).
- ACY02 found that doses higher than those included in the acyclovir label at the time of the study were well tolerated ([PMID: 27977557](#)).
- **Key Outcome:** Treating neonatal HSV may require higher doses of acyclovir than what was noted in previous dosing instructions, and these higher doses are well tolerated in multiple neonatal populations. As a result of this research, the U.S. Food and Drug Administration (FDA) updated the acyclovir label in 2019.

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.
 - ACY01: <https://dash.nichd.nih.gov/study/15961>
 - ACY02: <https://dash.nichd.nih.gov/study/15895>
- ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT00942084>
- FDA Label: <https://bit.ly/2R03JyZ>

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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