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 = glossary definition

ISV Study Basics



ISV is a Trial of *ACE Inhibition*  in Infants with Single *Ventricle* . The short title for this study is ISV. This study was being done to see if giving a medication called Enalapril (an ACE inhibitor) will improve a baby's growth and heart function in the first year of life. The study began on August 25, 2003 and the last infant was enrolled in May 2007 with 230 babies enrolled.

Who was in the study?



Children with a single *ventricle*  (lower pumping chamber) heart instead of 2 ventricles were in the study if they:

- Were less than 45 days of age and stable
- Were born no earlier than 35 weeks and weigh at least 2.5 Kg at birth (about 5½ pounds)
- Planned to have a Glenn shunt surgery
- Has not been on an ACE inhibitor for more than 7 days

What happened during the study?

Each qualified child was *randomly assigned*  to one of two treatment groups. One group received Enalapril and the other group received a *placebo* . Babies were followed until they reached 14 months of age.

During the study period, the following data was collected:

- Blood tests periodically to make sure that the medicine was well tolerated.
- *Echocardiograms*  prior to starting the study, prior to the Glenn surgery and again at 14 months of age.
- Height and weight was checked prior to starting the drug, at 14 days, prior to the Glenn surgery and again at 14 months.
- *Neurodevelopmental examination*  was done at 14 months of age.

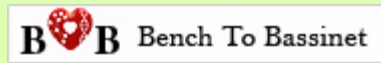
What were the results of the study?

This trial ended on July 8, 2008. The main thing that we learned from the study is that the ACE inhibitor medication called Enalapril did not provide a benefit for a baby's growth, heart function, or development at 14 months of age.

What we learned may or may not apply to your child. These findings are based on all 230 children, and your child's result may be different.

The PHN is grateful to all of the families who participated in this study. The results from this study has helped us to learn more about improving the care of children with a single ventricle heart defect. The Pediatric Heart Network plans to use these results to design additional studies in the near future.





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