

PHACS SMARTT Protocol: Participant Summary

Title: Safety of *In Utero* and Neonatal ARV Exposure: Cognitive and Academic Outcomes in HIV-exposed, Uninfected Children Age 5-13 Years

Title in Plain Language: How HIV Medicines Affect How Children Think and Learn

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Introduction: This study checked the safety of HIV medicines taken by pregnant women and their babies by looking at how children ages 5 to 13 think and learn.

Background: Many children born to mothers with HIV do not get the virus because mothers take HIV medicine before the babies are born and babies take HIV medicine in the first weeks of life. Some medicines and infections that babies are exposed to before and after birth can have an effect on how they learn, so it is important to see whether HIV medicines influence the children's learning as they get older.

Who Participated: A group of 810 children who were enrolled in SMARTT and were born to mothers with HIV participated in this study.. Another group of 96 children, born to mothers without HIV, also participated. In both groups, almost half the children were boys, about 75% were black, and 20-25% were Hispanic. The groups were similar to each other in important ways like prematurity and birth weight.

What We Did: The children in both groups took learning tests starting when they were at least 5 years old. The tests measured how well they could solve problems, use language, read, spell, and do arithmetic. We compared test scores according to the mothers' HIV status and the medicines they took before and after birth.

What We Found: We did not find a difference in test scores for children whose mothers took certain kinds of HIV medicines compared to children whose mothers did not. Most of the children were right where they should be for their age. A few medicines were related to lower scores on some parts of the test, and a few were related to higher scores. Some things like lower household income and mother's alcohol use during pregnancy were related to lower scores on some parts of the test.

What We Learned: The results of this study suggest that HIV medicines taken during pregnancy and the first weeks of the baby's life are not harmful to children's learning. We will continue following these children to see how they do in school as they get older.