

## **PHACS SMARTT Protocol PARTICIPANT SUMMARY**

**Title:** Point of Care Lactate Levels in a U.S. Prospective Cohort Study of HIV-Exposed Children with *In Utero* and Neonatal Exposure to Antiretroviral Therapies.

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**Study Description:** The SMARTT study was designed to look for any side effects of HIV medicines taken by a mother during pregnancy on her baby. Researchers have been concerned that some medicines used to treat HIV may cause problems with how cells make energy using something called “mitochondria”. Increased amounts in the blood of a chemical called “lactate” may be associated with problems in mitochondria. They use lactate levels in the blood of the babies as a way to look for problems with mitochondria.

Measuring lactate in babies is hard. Doing this requires taking blood from the arm without a tourniquet using a test called a venous lactate. Newer, easier techniques have been developed to test lactate which take blood from a finger stick. We call this POC lactate. In SMARTT, all children get a POC lactate test. If the result is high, then they get a venous lactate test.

For this study we wanted to see if the HIV medicines the mothers took during pregnancy affected the POC lactate levels in the children, since this might tell us if there were problems with the children’s mitochondria. To do this, we looked at how often lactate levels were high in children of different ages. We also wanted to see if the POC method is an accurate test. To do that, they compared the results of the POC and venous lactate tests.

**Study Population:** We compared 992 children in SMARTT who had study visits between September 2007 and August 2008. 811 children (82%) had at least one POC lactate measure. About half were girls. Nearly two-thirds of the children were black. The children ranged from newborns up to 12 years and 11 months.

**Results:** The average POC lactates varied significantly by age. Of the 19 children with high POC lactate, 15 had venous lactates done. 10 of the 15 children had high venous lactates as well.

**Conclusions:** High lactates were observed and were more common in infants younger than 6 months of age than older infants. Also, among babies with high POC lactate levels, the POC lactate test matched the venous lactate test well. Therefore, testing of lactate by fingerstick may be a useful and a rapid way to test for potential effects of ARVs.

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