



UNIVERSITY OF WASHINGTON
INTERNATIONAL CLINICAL RESEARCH CENTER
PARTNERS PrEP STUDY

PrEP Used in Pregnancy Does Not Increase Poor Birth Outcomes

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Poster #934. For more information, please contact Renee Heffron: rheffron@uw.edu

PARTNERS DEMONSTRATION PROJECT



Background

- Safety data from women using PrEP throughout pregnancy are very limited.
- Current recommendations for women using PrEP who become pregnant include counseling with the choice to continue or discontinue PrEP.

Methods

Interventional study population (PrEP-exposed):

- Partners Demonstration Project women (n=334) who became pregnant while using PrEP (n=30)
- Open-label FTC/TDF provided to participants at 4 research sites in Kenya and Uganda

Comparison group (PrEP unexposed):

- Partners PrEP Study women randomized to placebo (n=621) who became pregnant (n=79)
- Placebo-controlled trial at 9 research sites in Kenya and Uganda

Study procedures & statistical methods

- Monthly study visits during pregnancy for both groups; quarterly visits for infants after birth
- Pregnancy outcomes compared using generalized estimating equations – pregnancies with duration <8 weeks excluded
- Sex and age-adjusted z-scores calculated using WHO growth standards and a two-sample t-test was used to test for differences at each point in follow up

Participant characteristics

PrEP exposed

- N=30 pregnancies, 30 women

- Median age: 25 (IQR 21-28)

- Median prior children: 2 (IQR 1-2)

PrEP unexposed

- N=85 pregnancies, 79 women

- Median age: 28 (IQR 24-33)

- Median prior children: 2 (IQR 1-4)

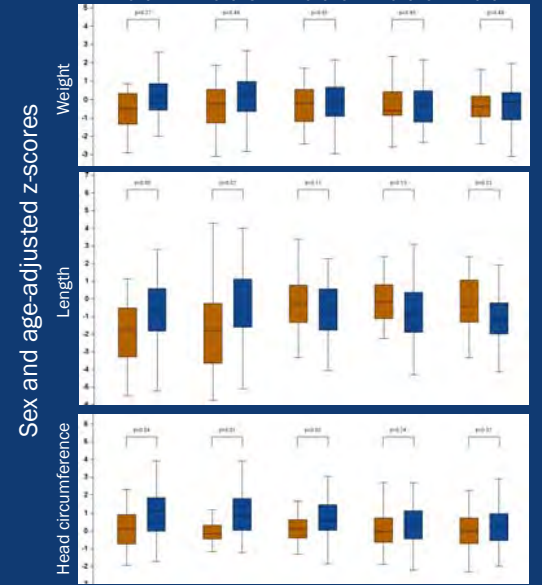
Pregnancy outcomes

	PrEP-exposed	PrEP-unexposed	OR (95%CI)* p-value
Preterm delivery	0	5 (7.7%)	0.4 (0-2.3) p=0.4
Pregnancy loss	5 (16.7%)	20 (23.5%)	0.8 (0.3-2.5) p=0.7
Congenital anomaly	0	5 (7.7%)	Fisher's exact p=0.3

*Adjusted for maternal age at study enrollment

Infant growth

PrEP-exposed PrEP-unexposed



Conclusions

- Pregnancy loss and preterm delivery similar in PrEP-exposed and unexposed pregnancies
- Infant growth characteristics were similar at 12 months; early detriments in PrEP-exposed babies appear to have caught up by 12 months