

Post Exposure Prevention (PEP) Study

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Project Description: Our research group recently conducted a Post Exposure Prevention (PEP) feasibility study in which over 400 individuals exposed to HIV-1 via sexual contact or recreational drug use (index case) were successfully recruited, retained, and assessed. This second PEP study is a randomized trial to determine whether enhanced (multi-session) risk reduction and adherence counseling is equivalent to standard (2 session) risk reduction and adherence counseling in terms of subsequent demand for repeated courses of PEP, self-reported risk behaviors, documented STDs, and adherence to PEP medications. To be included in this study, participants must report an HIV exposure during the previous 72 hours. Participants are randomized into either the enhanced or standard counseling group and followed for one year. Self-reported measures of HIV-related risk behavior are collected at baseline, 6 months, and 12 months. The study will enroll 600 index participants and all available and consenting source cases.

Significance: PEP has two promising possibilities: 1) it may prevent HIV infection and 2) it may be a viable way to attract high risk uninfected individuals into counseling. But considerable uncertainty remains about how to integrate PEP into existing clinical and prevention programs. Because it was felt that risk reduction counseling was essential to prevent disinhibition, the PEP feasibility study provided intensive (5 session) prevention counseling as well as adherence counseling. However, multi-session counseling is very resource-intensive. The primary aim of this second PEP study is therefore to assess whether PEP medications must be offered with an enhanced counseling program, or if standard HIV pre- and post-test counseling and routine adherence counseling will result in equivalent risk behaviors following PEP.

Interesting Findings: The project has recruited 490 index and 54 source participants. Of the 490 index participants, 471 are male, 16 are female, and 3 are transgender. The mean age is 35 years, and there is a diverse racial distribution (70% White; 14% Latino; 5% African American; and 11% other). The vast majority (93%) of index cases reported the risk of HIV exposure via sexual transmission.