

CAB-LA Clinical Trials: Further information and evidence

Difference between clinical trials for oral PrEP and CAB-LA

There is a difference in how efficacy studies for oral PrEP and CAB-LA were done. Oral PrEP was compared with a placebo, and CAB-LA was compared to oral PrEP.

PrEP

Oral PrEP evidence

- Clinical trials compared oral PrEP to a placebo. This is because there were no other prevention methods available other than condoms, which were therefore the standard prevention method at that time.
- These studies showed oral PrEP reduced the risk of HIV *by about 90% or more*, when taken as directed, compared to HIV rates in those taking a placebo.
- However, a lot of the studies showed that participants struggled to adhere to the daily dosing (taking a tablet daily).



CAB-LA Evidence

- Clinical trials of CAB-LA compared CAB-LA to oral PrEP, as oral PrEP was approved at that point, and was considered the standard at that time.
- CAB-LA users experienced even greater reduction in HIV risk *by about 80% compared to oral PrEP* users, depending upon sex at birth:
 - Men who have sex with men and transgender women who have sex with men = CAB-LA was 66% more effective than oral PrEP use.
 - Women = CAB-LA 88% more effective than oral PrEP use.

Effectiveness of CAB-LA – key message



So what does this tell us about CAB-LA effectiveness?

Due to the differences in how the oral PrEP and CAB-LA studies were conducted, **efficacy of CAB-LA compared to placebo is not known, since no studies were conducted that compared CAB-LA to a placebo.**



So why wasn't a study done for CAB-LA which compared it to a placebo such as had been done for oral PrEP previously?

Once oral PrEP was proven to protect against HIV, future studies could no longer ethically randomise participants to receive a placebo, as there was an existing standard of care that could protect them from HIV (being oral PrEP).



The key messages to be gleaned from these studies are:

- Both oral PrEP and CAB-LA greatly reduce HIV infection risk when used as directed
- CAB-LA yielded the greatest reduction in HIV infection risk, even more than oral PrEP
- Greater protection with CAB-LA may have resulted, in part, from better adherence to bi-monthly injections vs. daily dosing of oral PrEP