



PrEP Impact PGD

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Purpose of PrEP Impact Trial

- 1.** To measure PrEP-eligibility, PrEP-uptake, duration of PrEP-eligibility and duration of PrEP-use (PrEP prevention care continuum) among Genitourinary Medicine (GUM) clinic attendees
- 2.** To determine whether or not incident HIV infections in trial participants are due to non-adherence or biological failure
- 3.** To measure change over time in HIV diagnoses and incidence rate in those at high HIV risk
- 4.** To measure change over time in bacterial STI diagnoses and incidence rate in those at high HIV risk
- 5.** To measure the PrEP 'prevention care continuum' by clinic throughput and in different regions.

Plan

- What is PrEP?, how does it work?
- The evidence behind PROUD and EVB
- What are HIV seroconversion symptoms?
- Dosing and how to choose the regimen
- A little test to ensure you understand the PGD



Ricovir / Truvada

- Bioequivalence is a term in pharmacokinetics used to assess the expected in vivo biological equivalence of two proprietary preparations of a drug. If two products are said to be bioequivalent it means that they would be expected to be, for all intents and purposes, the same..and produce the same effect at the site of physiological activity.

PROUD the results..



- 545 msm, randomised use 50% on drug 50% not for 18/12
- Immediate arm- 3 positives (one who was within window at enrolment, other 2 were not adherent)
- Deferred- 19 new infections
- 86% effective in the real world
- Condom use didn't change, neither did the number of partners
- STS and CT up, this is across all GUM patients we see

IPIRGAY the results...

- 400 participants, half given Truvada half placebo (justified as drug still not certain to prevent HIV) over 2.5 years.
- Mean average of 15 pills per person per month used.
- 19 HIV infections, 3 at enrolment, 2 pos on drug 14 on placebo, the 2 'on' the drug-at their pill count- returned 58 and 60 respectively from the 60 they were given.
- So 86% effective

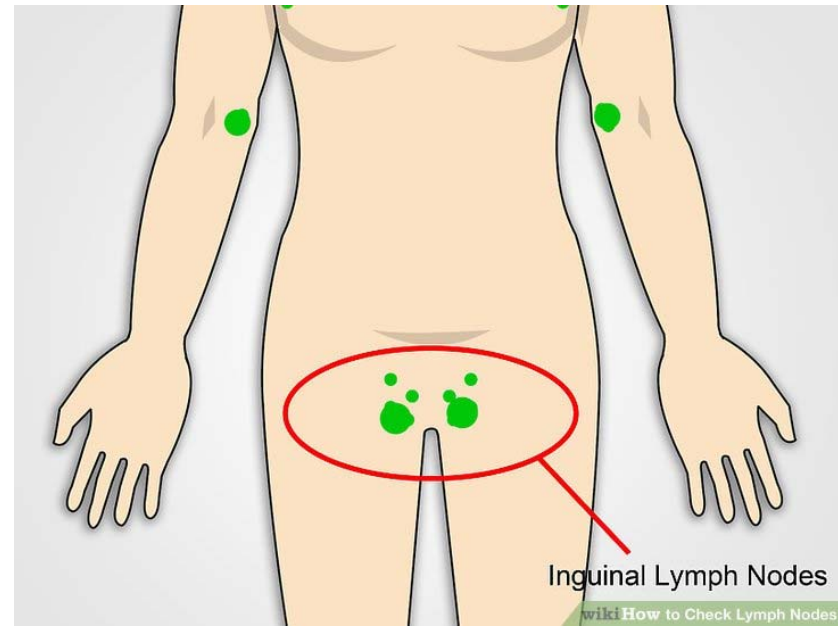
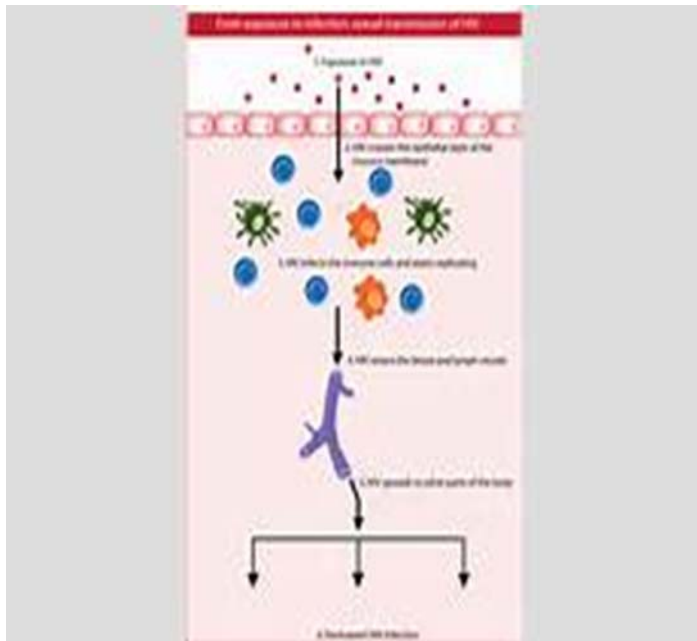


How the drug works..

- ‘Truvada’ works by tricking reverse transcriptase into thinking it is one of these molecular building-blocks. However, it is just different enough that when used to create DNA, Truvada actually stops the DNA from being made. Without DNA, HIV cannot multiply. It *starts* to reach the tissues in just 20 mins and *peaks* at 16 hours



Where is the drug?



Your assessment of the patient, is HIV a concern?

- HIV seroconversion / acute HIV syndrome occurs in 30-50% of new infections, sx range from mild to severe..
- fever, headache, muscle/joint aches and sore throat, sudden appearance of swollen lymph nodes and
- 2 out of 5 have maculopapular rash, pink to red with raised areas often joining together



Monitoring tests- abnormal results

If you notice any of the following changes on monitoring tests these must be reported to a Doctor;

1-Elevated Creatinine

2-Proteinuria



Daily or EBD

- EBD can only be used by cis-gay, bisexual men and men who have sex with men who's principal HIV risk is through condomless anal sex
- Participants can be guided by the nurse as to which schedule is appropriate for them taking into account;
- Frequency of sex
- Anticipated adherence
- Other medical conditions
- Patient choice
- Participant population

Daily dosing

- Participants require 7 days of pills to gain effective protection.
- If they are considering stopping they need to continue 7 days of pills from the last UPSI
- The pill should be taken ideally at the same time each day with or just after food

EBD

- Participants require 2 tablets 2-24 hour before sex. Single doses should then be taken at 24 and 48 hours after the initial dose.
- At least 2 doses of the drug need to be taken after the last sex occurred
- Unlike online PREP patients, participants in the trial always need to double dose before each new episode of UPSI even if <7 days have elapsed between the initial episode

Off license use

EBD is an off license use of the medication

Patients must be;

- Fully informed of risks and benefits
- That's its use is outside its product license
- Give verbal consent for use outside its product license
- This must be documented in the notes
- Participants must be given the option of seeing an appropriate Dr/Independent Nurse Prescriber

Options for taking the medication

- The tablet can be swallowed whole

Or



Can be disintegrated in approximately 100ml water, orange juice or grape juice and taken immediately

AT EVERY VISIT.....

You must check....

1. That the patient is still eligible for PrEP
2. That they wish to continue
3. Adherence i/e any risk / UPAI off drug



Before the patient leaves

You should clarify;

1. Adherence and dosing
2. Side effects and what to do if these occur
3. Risk of other STI's/safe sex
4. To report any new medicines to prescriber/pharmacist to check for interaction
5. Date of out of window HIV test (if needed)

