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Daily Doxycycline in MSM on PrEP for Prevention of Sexually Transmitted Infections

The DuDHS Study

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BACKGROUND

- Sexually transmitted infections (STI) occur in high rates in men who have sex with men (MSM)
- Recent work on daily doxycycline chemoprophylaxis against STIs (“STI PrEP”) has shown promise
 - Bolan *et al.* (*Sex Transm Dis* 2015): pilot study of doxycycline PrEP in 30 MSM; significant reduction in all STIs.
 - Molina *et al.* (*Lancet Infect Dis* 2018): IPERGAY substudy in 232 MSM on doxycycline PEP; significant reduction in syphilis and chlamydia.
- The aim of this pilot study was to determine STI outcomes in HIV-negative MSM taking both HIV and STI PrEP

METHODS

- Randomized, controlled pilot trial (n=52)
 - HIV-neg MSM or transgender women (TW) with prior syphilis
- Participants randomized 1:1 to 48 weeks of HIV PrEP with tenofovir/emtricitabine (TDF/FTC) in one of the following arms:
 1. Immediate doxycycline (IMM): doxycycline 100mg daily x 48w
 2. Deferred doxycycline (DEF): doxycycline 100mg daily starting at w24
- Followed every 3 months:
 - STI and HIV screening; tolerability and acceptability; tetracycline resistance (nares for *S. aureus* culture via disc diffusion); adherence (pill counts, doxycycline drug levels); questionnaires on sexual behaviour; rectal microbiome.

RESULTS

- 52 participants recruited: 51 MSM, 1 TW; median age 34 (IQR 29-43)
- **No participants on doxycycline developed syphilis or chlamydia**
 - Receipt of doxycycline associated with *reduced likelihood of any STI*
 - Odds ratio 0.18 (95% CI: 0.05-0.68; p=0.011)
 - Chlamydia: 10 cases in DEF (81.83 per 100PY) vs. none in IMM in first 24w (p=0.001). Nil thereafter.
 - Syphilis: 1 case in DEF (8.16 per 100PY) vs. none in IMM in first 24w (p=0.98). Nil thereafter.
 - Gonorrhoea: 8 cases in DEF (57.14 per 100PY) vs. 4 cases in IMM (31.37 per 100PY) in first 24w (p=0.505). 1 case in IMM post-24w.
- **Tetracycline resistance** in *S. aureus* in 1/3 and 3/6 samples at w24 and w48, respectively, in IMM arm; 1/2 in DEF arm at w48.
- **Self-reported adherence** ($\geq 95\%$): 89.5% and 72.2% in IMM and DEF arm, respectively, at 48w.

DISCUSSION

- The use of doxycycline at a dose of 100mg daily reduced the incidence of chlamydia; we were unable to ascertain the impact on syphilis.
- Self-reported adherence was excellent
- These findings, along with our findings demonstrating the development of tetracycline resistance in commensal organisms and other markers of adherence need to be re-examined in a larger study.
- Stay tuned:
 1. Full results for this study are forthcoming.
 2. The Doxycycline as an Intervention for STI ChemOprophylaxis (DISCO) Study: Recently funded for multi-site, three-arm RCT of STI PrEP vs. STI PEP vs. Standard of care (n = 500).

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**Questions and
comments welcome:**

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