# FINAL RESULTS OF ANRS 174 DOXYVAC: A RANDOMIZED TRIAL TO PREVENT STI IN MSM ON PREP

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**Background:**
STIs rates are increasing among MSM and new strategies are needed.

**Methods:**
MSM on PrEP with a history of STI, were randomized in an open-label factorial design trial to receive doxycycline PEP (200 mg within 72h of condomless sex) or no PEP (2:1); and 2 shots of the 4CMenB vaccine or no vaccine (1:1). Participants were tested at baseline, every 3 months and when symptomatic for *N. gonorrhoeae* (GC) and *C. trachomatis* (CT) by PCR in throat, anus and urine with serologic tests for syphilis. The co-primary endpoints were: the incidence of first episode of CT or syphilis with Doxy PEP and the incidence of a first episode of GC with the vaccine.

**Results:**
Between January 19, 2021, and September 19, 2022, 556 MSM were randomized and 545 were analyzed. Median follow-up: 14 months. There was no interaction between the two prevention strategies for the primary endpoints. The incidence of a first episode of CT or syphilis was 8.8 per and 53.2 per 100 PY in the Doxy PEP and no PEP arms, respectively (aHR: 0.17; 95%CI: 0.12-0.26). The incidence of a first episode of GC was 45.5 and 68.4 per 100 PY in the Doxy PEP and no PEP arms, respectively (aHR: 0.67; 95%CI: 0.52-0.87) with increasing rates of high-level tetracycline resistance in the Doxy PEP arm. The incidence of a first episode of GC was 58.3 and 77.1 per 100 PY in the vaccine and no vaccine arms, respectively (aHR: 0.78; 95%CI: 0.60-1.01) and the incidence of cumulative episodes was 57 and 64.4 per 1000 PY, respectively (aIRR: 0.89 (0.71-1.11). A single drug-related SAE was reported.

**Conclusion:**
Doxy PEP significantly reduced the incidence of CT and syphilis and to a lesser extent of GC. 4CMenB vaccine did not show a significant impact on the incidence of GC.

**Disclosure of Interest Statement:**
The Doxyvac study has been funded by ANRS/MIE. Roche diagnostic provided the PCR tests for CT and GC.
JM Molina has received honoraria for advisory board with Gilead, Merck and ViiV outside this study.