

Titel: Incidence rates of sexually transmitted infections in men who have sex with men and who are at substantial risk of HIV infection – a meta-analysis of data from trials and observational studies of HIV pre-exposure prophylaxis

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1. Participants diagnosed with at least one STI

For the outcome '**participants diagnosed with at least one STI**', we obtained data from one placebo-controlled trial¹, the PrEP group of an open-label trial,² and four cohort studies.³⁻

⁶ This yielded a cumulative 2454.2 person-years of follow-up. Incidence rates ranged from 34.3/100py (95%-CI: 29.2-40.3) in the placebo-controlled RCT to 65.8/100py (95%-CI: 59.0-73.5) in a cohort study. Our overall pooled estimate was 52.5/100py (95%-CI: 41.9-65.8, $I^2=93.6\%$). Data from the three studies conducted in Europe^{2, 5, 6} had similar incidence rates with a pooled estimate of 63.3/100py (95%-CI: 58.5-68.4, $I^2=0$), whereas the incidence rates in two cohort studies conducted in the USA^{3, 4} differed substantially: 40.2/100py (95%-CI: 36.2-44.7) and 63.0/100py (95%-CI: 52.4-75.7). When considering only the three studies that fulfilled the quality criteria for our sensitivity analysis,²⁻⁴ we estimated incidence rates ranging from 40.2/100py (95%-CI: 36.2-44.7) to 63.0/100py (95%-CI: 52.3-75.7), with an overall pooled estimate of 53.8/100py (95%-CI: 38.8-74.6, $I^2=93.2\%$).

2. Data on anogenitals warts, herpes simplex, and other STIs

Anogenital warts

One placebo-controlled RCT⁷ reported data on condylomata acuminata, but whether only incident or all prevalent cases were counted was not specified. We used this study to calculate a mean point prevalence rate, which was 4.44% (95%-CI: 3.91-5.03). One study reported data on "anogenital HPV"⁸. Since this was not further specified, we did not include this data.

Herpes simplex

No study reported on the incidence of clinically manifest HSV-infection. Data for the incidence of HSV-2 seroconversion of participants who were seronegative at baseline were reported separately for the placebo group in one RCT⁹. During a follow-up of 1071py, a seroconversion rate of 5.6/100py (95%-CI: 4.4-7.2) was seen. One RCT reported the incidence of genital herpes without specification of the group allocation of the participant⁸; this data was therefore

not included. One study reported on the incidence of genital ulcers⁷. Since this outcome was not further specified and may imply several differential diagnoses, these data were not further evaluated.

Other STI

One placebo-controlled RCT⁸ reported the incidence of one case of **molluscum contagiosum**. It remained unclear, whether this was a chance finding or whether participants were routinely checked for skin changes corresponding to molluscum contagiosum. One cohort study¹⁰ reported that no cases of **trichomonas** occurred during follow-up. It was unclear, whether participants were routinely screened for trichomonas infection.

3. References

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