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 trial, the PrEP group of an open-label trial, and four cohort studies. 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, I²=93.6%). Data from the three studies conducted in Europe had similar incidence rates with a pooled estimate of 63.3/100py (95%-CI: 58.5-68.4, I²=0), whereas the incidence rates in two cohort studies conducted in the USA 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, 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, I²=93.2%).

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

Anogenital warts

One placebo-controlled RCT 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”. 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 RCT. 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 participant; this data was therefore
not included. One study reported on the incidence of genital ulcers. Since this outcome was not further specified and may imply several differential diagnoses, these data were not further evaluated.

**Other STI**

One placebo-controlled RCT\(^8\) 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 study\(^10\) reported that no cases of *trichomonas* occurred during follow-up. It was unclear, whether participants were routinely screened for trichomonas infection.
3. References