

Asmal, H. (2008). NMB - common adverse effect among women on injectible contraceptives: experiences from mdp 301 Microbicides 2008. Delhi.

Introduction: MDP 301 is a phase III microbicide trial. Any episode of NMB (non menstrual bleeding) is regarded as an adverse event, with grade 3 (defined as heavy bleeding like menses for >4 days) requiring expedited reporting for safety. NMB is a common side effect of injectible contraceptives such as Norethisterone Enantate (Nuristerate) and Medroxyprogesterone Acetate (Depo). A recent review of randomised controlled trials confirmed no difference in bleeding and spotting events between the two injectibles 1. Objective: The objective of the study was to determine contraceptive practices of those reporting NMB at follow-up and to determine if these women had experienced NMB as a pre-existing condition. Methodology: This was a retrospective CRF review of the first 1412 women enrolled from 17/11/2005 until 23/08/2007. The first episode of NMB reported at follow-up, related contraception use and previous medical history were analysed. Results: At follow-up, 291 (20.6%) out of 1412 enrolled women reported NMB as an adverse event. Of these 291 women, 79 (27%) had reported NMB as a pre-existing condition prior to commencing study gel. 239 (82.1%) of the 291 women were also on concomitant injectibles contraceptives which are a known risk factor for NMB. At that point in time, 44% of the entire cohort of enrolled women were on injectibles contraceptives. Conclusion: Menstrual irregularities at follow-up in women on injectible contraceptives requires careful consideration when assessing relationship to study product, as these are frequent occurrences among women using injectible contraception. A significant proportion of these women have reported NMB as a pre-existing condition prior to commencing study gel. References: 1 Draper BH, Morroni C, Hoffman M, Smit J, Beksinska M, Hapgood J, Van der Merwe L. Depot medroxyprogesterone versus Norethisterone oenanthate for long-acting progestogenic contraception. Cochrane Database of Systematic Reviews 2006, Issue 3.