Table S1: Characteristics of Studies Providing Individual Patient Data

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study | N\* | N used† | Active treatment‡ | Control treatment | Allocation ratio | BV definition | Gestation at randomization | Sonography for gestational age |
| Hauth, 1995 | 263 | 256 | MZ, 250 mg tid x 7; EM 333 mg/d x 14, repeat if positive at 2-4 wks | Matching placebos, repeated if still positive at 2-4 wks | 2:1, variable block, computer generated | ¾ Amsel criteria, Nugent score 7+ | 22-24 weeks | Yes |
| NICHD BV, 2000 | 1944 | 1910 OR; 1908 HR | MZ, 2 gram x 2, on 2 occasions regardless of positivity | Matching placebo | 1:1, urn, stratified by study site | Nugent score 7+ and pH>4.4 | 16-23 weeks | Yes, before randomization |
| NICHD TV, 2001 | 238 | 233 | As NICHD BV | As NICHD BV | As NICHD BV | As NICHD BV | As NICHD BV | As NICHD BV |
| Odendaal, 2002 | 277 | 276 | MZ, 400 mg bid x 2 days repeated at 4 weeks if still positive | Vitamin C, 100 mg bid x 2 days repeated at 4 weeks if still positive | 1:1, balanced block design | ¾ Amsel or Lacto <2+ (Spiegel) | 15-26 weeks | Yes if <24 weeks, no otherwise |
| Ugwumadu, 2003 | 410 | 391 | Oral CM, 300 mg bid x 5, | Matching placebo | 1:1, simple randomization | Nugent score 7+ | 12-21 weeks | Yes (could be done after randomization) |
| Lamont, 2003 | 417  412§ | OR 407  402§  HR 398 393§ | Topical CM, 3 evenings | CM vehicle, 3 evenings | 1:1, random block | Nugent score 7+, study also included women with scores 4-6§ | 13-20 weeks | Yes, before randomization |
| NICHD fFN, 2003 | 190 | 185 OR;  184 HR | MZ 250 mg tid, EM 333 mg 4/d x 10 days | Matching placebos | 1:1 urn, stratified by study site | Nugent score 7+ | 21-25 weeks | Yes, before randomization |
| Kiss, 2004 | 375  372§ | 359  356  OR only | Topical CM, 6 days; oral CM 200 bid x 7 if positive at 24-27 wks (topical MZ if positive for TV | None, all women screened, and then randomized to receive screening results | 1:1, computer generated | Nugent score 7+ | 15-19 weeks | Yes (could be done any time up to 19 wks) |
| Shennan, 2006 | 13 | 11 | MZ, 400 mg tid x 7 d | Matching placebo | 1:1, stratified by week of positive fFn and clinical site | Nugent score 7+ | 24-27 weeks | Yes |
| Larsson, 2006 | 819  800§ | 809  790§ | Topical CM, 7 evenings, repeated if positive at 24 or 31 weeks | None (Zelen design) | 1:1, block size 10 | Nugent score 6+, changed to Hay-Ison score | 10-14 weeks | Best clinical estimate from Swedish Medical Birth Registry |
| Goldenberg, 2006 | 1170|| | 1101  1085¶ | MZ, EM 250 mg tid x 7d | Matching placebo | 1:1, permuted block, stratified by clinical site | Nugent score 7+ | 20-24 weeks | No |
| Gupta, 2013 | 800 | 0 | Topical CM 100 mg; clotrimazole 100 mg, 7 evenings | None | 1:1 computer generated | Nugent score 7+ | 12-24 weeks | If available; number with sonogram unknown |
| Hoffman, 2018 | 68 | 68 | CM, 300 mg bid x 5 d | Matching placebo | 1:1, blocks of 6 | Nugent score 7+ and pH 5+ | 13-20 weeks | If available; sonography not routine |

\* Number of observations in received data file

† Number included in analysis, typically excluding women with missing outcome, gestation at randomization and/or obstetrical history. The duration of pregnancy is used for the hazard ratio (HR), whereas an indication of birth before 37 weeks is used for the odds ratio (OR); the number for each analysis is indicated if they differ.

‡ MZ=metronidazole; CM=clindamycin; EM=erythromycin

§ Data provided do not allow women with abnormal flora and BV to be differentiated

|| Estimated number of women with BV based on published paper. Received data excluded women who were missing outcome data.

¶ Number after excluding twin pregnancies