|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Table S3: Risk of bias of studies providing individual data | | | | | | | |
|  | Random sequence generation | Allocation concealment | Blinding of participants and personnel | Blinding outcome assessment | Incomplete outcome data | Selective reporting | Other |
| Hauth, 1995 | + | + | + | + | + | ?\* | + |
| NICHD BV, 2000 | + | + | + | + | + | +† | + |
| NICHD TV, 2001 | + | + | + | + | + | +† | + |
| Odendaal, 2002 | + | - | + | + | + | ?\* | + |
| Lamont, 2003 | + | + | + | + | + | ?\* | + |
| NICHD fFn, 2003 | + | + | + | + | + | + | +‡ |
| Ugwumadu, 2003 | + | + | + | + | + | ? | +§ |
| Kiss, 2004 | + | + | -|| | ?|| | + | ?\* | + |
| Goldenberg, 2006 | + | + | + | + | +¶ | + | + |
| Larsson, 2006 | + | + | -|| | ?|| | ?# | ?\* | ?\*\* |
| Shennan, 2006 | + | + | + | + | + | + | ?†† |
| Gupta, 2013 | ? | ? | ? | ? | -‡‡ | ?\* | ?a |
| Hoffman, 2018 | + | + | + | + | + | + | + |

+ = low risk of bias; - = high risk of bias; ? = unclear risk of bias

\* Study protocol unavailable, therefore impossible to compare reported and planned outcomes.

† All primary and secondary outcomes in protocol were reported. Additional outcomes and subgroup analysis also reported. All were negative.

‡ Baseline difference in history of preterm birth differs between treatment and control groups in the entire study population, but not among the subset of BV+ women that are included in this meta-analysis.

§ Primary outcome in protocol agrees with outcome in published report. Protocol lists no secondary outcomes or planned subgroup analyses.

|| Some degree of unblinding is inevitable under the Zelen design employed. Since patients randomized to active treatment, and their managing clinicians, were aware of BV-positivity, clinical management (such as decision to deliver for a complication) might impact gestational age in these women. The degree to which this happened is speculative but we judge it to be limited.

¶ Pregnancy outcome data unavailable for 5.9% of BV+ women randomized to antibiotic and 7.3% of those randomized to placebo. Reasons for withdrawal did not differ substantially by treatment group.

# Small number of post-randomization exclusions not due to missing outcomes (twins, treatment outside of study, indicated preterm birth)

\*\* Target sample size not reached, no explanation provided.

†† Target sample size not reached, study terminated due to futility.

‡‡ Women who developed a pregnancy complication after randomization were excluded. Number of such women not provided.

a. Sample size calculation unclear.