## randomized, placebo-controlled trial with cefetamet-pivoxil in pregnant women with a poor obstetric history

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## **Abstract:**

OBJECTIVE: This study was undertaken to measure the impact of a single oral dose of cefetamet-pivoxil on pregnancy outcome in a population with substantial rates of low birth weight and high prevalence rates of maternal infections. STUDY DESIGN: A total of 320 pregnant women with a poor obstetric history, defined as a history of low birth weight or stillbirth, were randomized to receive a single oral dose of 2 gm of cefetamet-pivoxil or a placebo at a gestational age between 28 and 32 weeks. Patients were assessed at delivery and 1 week post partum for pregnancy outcome, postpartum endometritis, human immunodeficiency virus-1 and gonococcal infections. RESULTS: A total of 253 (79%) women gave birth at the maternity hospital, of whom 210 (83%) attended the follow-up clinic. Overall, 18.1% of these pregnant women were human immunodeficiency virus-1 seropositive, whereas 9.5% had antibodies against Treponema pallidum. There was a significant difference between cefetametpivoxil- and placebo-treated women in infant birth weight (2927 gm vs 2772 gm, p = 0.03) and low birth weight (< 2500 gm) rates (18.7% vs 32.8%, p = 0.01, odds ratio 2.1, 95% confidence interval 1.2 to 3.8). The stillbirth rate was 2.2% in the cefetamet-pivoxil group and 4.2% in the placebo group (not significant). Postpartum endometritis was found in 17.3% in the intervention arm versus 31.6% in the placebo group (p = 0.03, odds ratio 2.2, 95% confidence interval 1.1 to 7.6). Neisseria gonorrhoeae was isolated from the cervix in 5 of 103 (4.9%) women in the intervention and in 14 of 101 (13.9%) in the placebo group (p = 0.04, odds ratio 3.2, 95% confidence interval 1.1 to 10.5). CONCLUSION: A single oral dose of cefetamet-pivoxil administered to pregnant women with a poor obstetric history seemed to improve pregnancy outcome in this population with high rates of maternal infections. Larger studies should be carried out to examine the public health impact, the feasibility, and the overall cost/benefit ratio of this intervention