Ursodeoxycholic acid in the treatment of cholestasis of pregnancy: A randomized, double-blind study controlled with placebo

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Background/Aims: Intense pruritus and the risk of stillbirths and premature deliveries justify the search for an effective pharmacologic treatment of intrahepatic cholestasis of pregnancy. This study was designed to test the efficacy of ursodeoxycholic acid in maternal pruritus, the biochemical abnormalities and the outcome of pregnancy, in patients with intrahepatic cholestasis of pregnancy of early onset. Methods: Pregnant patients hospitalized in a secondary case-referral center with intense pruritus and abnormal serum levels of bile salts and aminotransferases, detected before week 33 of pregnancy, were randomly assigned to receive ursodeoxycholic acid, 1 g per day orally, or an identical placebo, until delivery, in a double-blind study. A 3-week trial period was chosen to compare drug and placebo effects. The follow-up was extended for 3 months after delivery. Results: Twenty-four patients entered the trial; eight had deliveries before 2 weeks of treatment and one dropped out. The