

# Outcome of pregnancy in a randomized controlled study of patients with asthma exposed to budesonide

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Background: Budesonide is the only inhaled corticosteroid to be given a category B pregnancy rating by the US Food and Drug Administration, based on observational data from the Swedish Medical Birth Registry. However, data from large randomized controlled trials are lacking. Objective: To compare pregnancy outcomes among patients with recent-onset mild-to-moderate persistent asthma receiving low-dose budesonide vs placebo. Methods: In a randomized, double-blind, placebo-controlled trial, 7,241 patients aged 5 to 66 years with mild-to-moderate persistent asthma for less than 2 years and no previous regular corticosteroid therapy received once-daily budesonide or placebo via dry powder inhaler in addition to their usual asthma medication for 3 years. This trial was followed by a 2-year open-label treatment period. The daily dose of budesonide was 400 µg for adults. The study included 2,473 females aged 15 to 50 years at randomization. Pregnancy was not an exclusion criterion (except for