

**Schatz M et al.** The safety of asthma and allergy medications during pregnancy. *J Allergy Clin Immunol* 100, 301-306, 1997

Type of study	Prospective cohort
Where	California
When	1978-1989
Characteristics of the starting cohort	Participants in the Kaiser-Permanente Prospective Study of Asthma Durin Pregnancy: women registering for prenatal care were asked to complete a questionnaire regarding their history of asthma or symptoms of asthma. All subjects with asthma were recruited to enter the study and evaluated at least monthly during pregnancy
Exposure definition	Intake before 14 weeks' gestation on the basis of gestational age at delivery. Corticosteroid use was categorized as follows: intranasal (for rhinitis), inhaled (for asthma), oral, inhaled total (with or without oral), inhaled only (without oral), any (intranasal, inhaled, oral)
Ascertainment of drug exposure	All medications used since conception were recorded on the subject's initial visit (<28 weeks). Thereafter, daily diary cards for all medications (name, strength, amount taken) were completed by the patient through the time of delivery
Size of the studied cohort	Exposed women: 1044 recruited; 824 in follow up; 824 singleton newborns Unexposed reference group women: 860 recruited; 678 in follow up; 678 singleton newborns
Exposed cohort	Newborns exposed to a group of drugs
Control cohort	Women without asthma who matched a previously entered subject with asthma on the basis of age, parity, and smoking, were recruited and contacted by phone at least every 3 months to remind them of study procedures. Diary cards for controls were mailed in after the women gave birth
Malformations definition	Not indicated
Malformations ascertainment	Not indicated
Prevalence of malformations among control offspring	Unexposed at anytime in pregnancy: B-agonists: 6.2%, theophylline: 5.3%, cromolyn: 4.9%, corticosteroids: 4.9%, antihistamines: 5.7%, decongestants: 4.9%
Analysis	- Chi square, linear trend analysis, Student's <i>t</i> test - Adjusted OR and 95% CI were estimated (logistic regression to control for potential confounders: age, parity, smoking, race, weight gain during pregnancy, maternal pulmonary function, acute asthmatic episodes, multiple medication exposure)
Strengths	- Exposures ascertained prospectively after initial visit - Evaluation of the study's power analyses - No differentiated recall bias between the exposed and non exposed groups
Weaknesses	- Exposure self-reported by women - Patient withdrawal: 14.3% (with asthma), 15.7% (control) - Definition and ascertainment of malformations not indicated - Incomplete information on reproductive end points (in e: abortions, stillbirths)
Main results	No significant relationships (all P values > 0.05) were identified between major congenital malformations and first trimester or any exposure to B-agonists, theophylline, cromolyn, corticosteroids, antihistamines, decongestants. In the multivariate

analyses, oral corticosteroids were independently associated with preeclampsia (OR 2.0, P=0.03)