

Castilla EE et al. Teratogenicity of misoprostol: data from the Latin-American Collaborative Study of Congenital Malformations (ECLAMC). *Am J Med Genet* 51, 161-162, 1994 (letter)

Type of study	Case-control
Where	Brazil, Venezuela, Argentina, Bolivia, Chile, Colombia, Uruguay
When	1991-1992
Cases	5,708 malformed newborns
Case prevalence among the population	Not indicated
Controls	5,708 non-malformed newborns
Exposure definition	Intake during the first trimester of pregnancy
Ascertainment of drug exposure	Not indicated (self-reported by women at interview)
Prevalence of exposure among controls	0.07%
Analysis	P value calculated according to the Poisson distribution
Strengths	- Good definition of the birth defects
Weaknesses	- The frequency of studied drug use recorded by the Collaborative Study represents an under-registration (illegal use) - Control newborns with no birth defects (risk of recall bias)* - No information on dosage in some cases - Possible confounding factors unreported
Main results	The available data suggest an association between high doses of misoprostol during early pregnancy and the occurrence of apparent vascular disruption defects, even if caution is needed in assuming a cause-effect relationship