

Shaw GM et al. High maternal vitamin A intake and risk of anomalies of structures with a cranial neural crest cell contribution. *Lancet* 347, 899-900, 1996 (*Letter*)

Type of study	Population-based case-control
Where	California
When	1986-1989
Cases	Orofacial clefts: 731 malformed newborns Conotruncal heart defects: 207 malformed newborns
Case prevalence among the population	Not indicated
Controls	Orofacial clefts: 734 non-malformed newborns Conotruncal heart defects: 481 non-malformed newborns
Exposure definition	Intake 1 month before to 3 months after conception (single vitamin A supplements + multivitamin supplements = over 10,000 IU/day)
Ascertainment of drug exposure	Specifically asked about vitamin supplements used by women, one of which was single supplement vitamin A
Prevalence of exposure among controls	Orofacial clefts: 1.2% Conotruncal heart defects: 1.5%
Analysis	OR and 95% CI were estimated
Strengths	- Population-based data set with nearly complete case ascertainment - Recall at an average of 3.5 years after delivery
Weaknesses	- Drug intake based on maternal report (risk of recall bias), information on dosage was indirect - Control newborns with no birth defects (risk of recall bias) - No information about characterization and definition of cases - Not indicated if the interviewers were aware of the case and control status - Not indicated the time of the interview after delivery
Main results	For orofacial clefts, the OR was 0.55 (95% CI 0.2-1.5), indicating no increased risk associated with vitamin A use. For conotruncal heart defects the OR was 0 (95% CI 0-2.2)