

# The safety of ondansetron for nausea and vomiting of pregnancy: a prospective comparative study

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**Objective** Ondansetron (Zofran) is a drug used for the treatment of nausea and vomiting caused by cancer chemotherapy. Despite the fact that it is not indicated, women are being prescribed this drug for the treatment of nausea and vomiting of pregnancy (NVP). There is a paucity of information on fetal safety for this indication. The objective of this study is to determine whether this drug increases the baseline rate of major malformations.

**Design** A prospective comparative observational study.

**Setting** Teratogen Information Services (TIS).

**Population** Pregnant women.

**Methods** Our three groups included women who were exposed to ondansetron and women exposed to (1) other anti-emetics and (2) non-teratogen exposures. All of the women called either our NVP Helpline or TIS at The Motherisk Program in Toronto, Canada, or The Mothersafe Program in Sydney, Australia.

**Main outcome measure** Rates of major malformation.

**Results** We have completed 176 pregnancy outcomes in each group. In the ondansetron cohort, there were 169 live births, 5 miscarriages, 2 therapeutic abortions, 6 (3.6%) major malformations and the mean birthweight was 3362 g [SD 525]. There were no statistical differences in any of the study endpoints between the ondansetron and the comparison groups.

**Conclusions** This drug does not appear (although the sample size is limited) to be associated with an increased risk for major malformations above baseline.

BJOG: an International Journal of Obstetrics and Gynaecology

September 2004, Vol. 111, pp. 940 – 943

DOI: 10.1111/j.1471-0528.2004.00236.x