

# Phyto.vig.gest.:a multicenter observational study on consumption and effects of drugs and food supplements in pregnancy

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In Italy, as well as in other countries, the potential harmful teratogenic effects of drugs, botanicals, food supplements and other licit substances assumed by pregnant women represent a major public health issue (**Ngoc 2006**). The exposure of chemicals contained in these products could be related to serious problems such as: death in utero, abnormal fetal development, functional deficit, structural malformations, and neonatal death (**FDA 2005**). Data regarding the majority of substances assumed during pregnancy provided by preclinical testing and clinical experience are still insufficient with respect to their safety, despite their consumption is common (**Schaefer 2011**). Only a few epidemiological studies have evaluated the actual prevalence of exposure of pregnant women to potential harmful substances. Currently, it appears crucial to assess the existence of a link between increased risk for pregnancy and consumption of these products. For this reason, we planned to conduct an observational multicenter study collecting data of women who recently delivered. The subjects will be recruited in three regions of Italy in eight centers of Gynecology and Obstetrics in Sicily, four in Emilia Romagna and three in Tuscany.

After delivery women will be interviewed face-to-face by trained 'monitors', who will fill a specifically designed and developed electronic form. The questions will inquire the following issues: sociodemographic characteristics, parity, medical problems before and during pregnancy, medical history of parents, drugs and supplements taken before and during pregnancy, exposure to cigarette smoking and consumption of alcohol, caffeine and illicit substances. Monitors will use clinical records to have additional informations about women and babies health outcome. The newborn data will provide details about weight, height, cranial perimeter, appearance, pulse, grimace, activity, and respiration score (Apgar score) at 10 minutes, and the presence of a other medical problem. Also data regarding fathers sociodemographic characteristics, medical status, previous medical problems, use of drugs, botanical and food-supplements, life style, exposure to cigarette smoking and consumption of alcohol, caffeine and illicit substances will be collected. Ninety days after delivery other informations about health outcome of the babies and lactation will be collect through a phone-interview. We suppose to recruit 200 subjects a year per each center. The duration of the study will be of 24 months. Results of the study will provide important useful data to better understand the impact of consumption of drugs and food supplements on pregnancy and to improve clinical obstetric practice and future prevention programs.

## References:

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