

Data on effectiveness of morning sickness drug may be flawed

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(HealthDay)—Pyridoxine-doxylamine (Diclectin), used to manage the

nausea and vomiting associated with morning sickness, may not be as effective as once believed, according to a new analysis published online Jan. 4 in *PLOS One*.

Nav Persaud, M.D., and Rujun Zhang, M.D., from St. Michael's Hospital in Toronto, reviewed 36,000 pages of documents from the U.S. Food and Drug Administration, including an unpublished 1970s study and a summary of the results. The investigators also obtained other documents from Health Canada through freedom of information requests.

The original trial was done in 14 U.S. clinics among 2,308 women who experienced [morning sickness](#) during their first 12 weeks of pregnancy. The women were randomly assigned to eight groups, one of which was given a placebo and the other seven a variety of drugs, including pyridoxine-doxylamine. Data from 1,599 women were analyzed. More [women](#) rated the drugs as moderate or excellent, compared with those given a placebo. For pyridoxine-doxylamine, 14 percent gave it a moderate or excellent rating.

Persaud said the earlier study's data about the effectiveness of pyridoxine-doxylamine are shaky at best. "We found two main problems with the [unpublished] study. Data were missing for 31 percent of participants. There are questions about the integrity of the data," Persaud told *HealthDay*. "The approval and prescribing of this medication are based on this study. The decision to approve this medication should be revisited. The prescribing of the [medication](#) should be revisited."

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