

Ginger was equivalent to pyridoxine hydrochloride (vitamin B6) for reducing nausea and vomiting in pregnancy

Smith C, Crowther C, Willson K, *et al*. A randomized controlled trial of ginger to treat nausea and vomiting in pregnancy. *Obstet Gynecol* 2004;103:639–45.

Clinical impact ratings FP/GP/Obstetrics ★★★★★☆ Obstetrics ★★★★★☆

Q In pregnant women who experience nausea and vomiting, is ginger equivalent to pyridoxine hydrochloride (vitamin B6) for controlling symptoms?

METHODS

	Design: randomised controlled equivalence trial.
	Allocation: concealed.*
	Blinding: blinded (patients, healthcare providers, and data collectors).*
	Follow up period: 3 weeks.
	Setting: a hospital in Adelaide, South Australia, Australia.
	Patients: 291 women who were 8–16 weeks pregnant (confirmed by ultrasonography). Exclusion criteria: signs of clinical dehydration, allergy to ginger or pyridoxine, or suspicion that symptoms were not related to pregnancy.
	Intervention: women were allocated to ginger, 350 mg capsule 3 times daily (n = 146), or pyridoxine, 25 mg capsule 3 times daily (n = 145), for 3 weeks.
	Outcomes: nausea, dry retching, and vomiting (Rhodes Index of Nausea and Vomiting Form 2; score 0–12, with higher scores indicating more symptoms); change in health status (MOS 36 Short Form Health Survey); and pregnancy outcomes.
	Patient follow up: 81%.
	*See glossary.

MAIN RESULTS

Treatment groups did not differ for overall reduction of symptoms (table). Ginger was therapeutically equivalent to pyridoxine for improving nausea (mean difference 0.2, 90% CI –0.3 to 0.8), dry retching (mean difference 0.3, CI 0.0 to 0.6), and vomiting (mean difference 0.5, CI 0.0 to 0.9). Evidence was insufficient for showing therapeutic equivalence for improving health status; only 2 of 8 health domains were statistically significant for equivalence. The

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treatment groups did not differ for spontaneous abortion, stillbirth, neonatal death, congenital abnormality, or pregnancy complications.

CONCLUSION

In pregnant women who have nausea and vomiting, ginger reduced their symptoms to the same extent as pyridoxine hydrochloride (vitamin B6).

Commentary

Nausea and vomiting are common symptoms of pregnancy and affect 50–80% of all women. The side effects of many traditional medications are frequently undesirable, and safety is a concern. A recent systematic review evaluating the effects of various therapies for nausea and vomiting in pregnancy¹ showed that antihistamines and, in 1 small trial, ginger were more effective than placebo at reducing nausea and vomiting. Pyridoxine showed benefit in the reduction of nausea, but its effect on vomiting was not as clear. A marked increase in rates of drowsiness and sedation (odds ratio 2.24, 95% CI 1.05 to 4.75) limit the efficacy of antihistamines. Neither ginger nor pyridoxine showed side effects similar to those of antihistamines. None of these therapies negatively affected pregnancy or fetal outcomes.

The randomised controlled trial by Smith *et al* directly compared the effects of ginger and pyridoxine. Study doses were similar to those showing effectiveness in earlier trials, and the 3 week intervention period was longer than that in many similar trials. Two potential problems were noted. Firstly, despite being blinded, several women in each group were aware of their assigned treatment. Secondly, women who were taking other agents for nausea and vomiting were allowed to continue them throughout the study. Despite these concerns, the numbers of “unblinded” women and those taking additional agents were similar in both groups, likely limiting the effects of any bias.

These points aside, the study findings support the efficacy of both ginger and pyridoxine for nausea and vomiting in pregnancy. Their limited side effect profiles make them attractive alternatives to traditional medication. The safety of pyridoxine has been well established.² As the authors note, although no concerns about ginger were raised in this trial, additional and larger studies are needed to confirm its safety.

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1 Jewell D, Young G. Interventions for nausea and vomiting in early pregnancy. *Cochrane Database Syst Rev* 2003;(4):CD000145.

2 Mazzotta P, Magee LA. A risk-benefit assessment of pharmacological and nonpharmacological treatments for nausea and vomiting of pregnancy. *Drugs* 2000;59:781–800.

Ginger v pyridoxine for nausea and vomiting in pregnancy*

Outcomes at 3 weeks	Ginger	Pyridoxine	RBR (95% CI)	NNH
Self reported overall reduction in symptoms	53%	55%	3.0% (–21 to 23)	Not significant

*RBR = relative benefit reduction. Other abbreviations defined in glossary.