

## Hypertension in pregnancy and statistical power

**H**ypertension in pregnancy is a major cause of maternal and fetal morbidity.<sup>1</sup> Preeclampsia, eclampsia, intrauterine growth retardation, and perinatal mortality are adverse effects associated with hypertension.

Approximately 10 percent of pregnant women are at risk for complications attributable to high arterial blood pressure.<sup>2</sup> Although the treatment of hypertension reduces the maternal risks,<sup>3</sup> the benefits for the fetus are not yet clear.<sup>4</sup>

The treatment of hypertension crises, one of the most dangerous types of hypertension in pregnancy may be obtained with efficacy using low dose nifedipine (5 mg per oral), or hydralazine (5 mg IM). Reducing the dosage is aimed at decreasing the risks of maternal hypotension and fetal death.<sup>5,6</sup>

Both drugs have about 90 percent efficacy in reducing blood pressure, but it is not known which drug carries less risk of adverse effects for the fetus. Suppose that one percent of fetal deaths could be attributed to one drug, and the other drug could be attributed with 0.5 percent; that means a 50 percent less chance of fetal deaths. **In order to have 90 percent power to detect the referred difference on the fetal attributable mortality rate to each of these drugs, a study of 14,000 women with hypertensive crises would be required.**<sup>7</sup>

Although doing a randomized clinical trial of such magnitude would be very difficult, it would certainly not be impossible - if the question were considered relevant for researchers, and more importantly, for funders. Similar situations, as are the cases of drugs adverse effects are

common in medical literature, and important because they represent human suffering and death.

A proposal for a randomized clinical trial has been prepared by the Eclampsia Trial Group, aimed at comparing magnesium sulfate with placebo. The sample size is estimated at 14,000 cases. The trial would be collaborative, with various groups in Europe and developing countries participating. The effort is worthwhile, as the prevention of eclampsia could prevent about 50,000 maternal deaths annually, 99 percent of which occur in the developing world.<sup>8</sup>

### REFERENCES

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