

# AntiEpileptic drug Monitoring in PREgnancy (EMPIRE): a double-blind randomised trial on effectiveness and acceptability of monitoring strategies

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**Disclaimer:** This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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## Plain English summary

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## Plain English summary

Pregnant women with epilepsy who take medication for their seizures may have a decrease in the drug levels in their blood. This may worsen seizures. Some hospitals in the UK use regular blood tests to check the amount of drug in the mother's blood and offer to increase the dose of the medication if the levels reduce. Most hospitals in the UK do not monitor drug levels because existing National Institute for Health and Care Excellence and Scottish Intercollegiate Guidelines Network guidelines recommend a strategy based on monitoring clinical features. There is a lack of evidence to support either management.

The AntiEpileptic drug Monitoring in PREgnancy (EMPiRE) study aimed to find out if routine blood tests to monitor drug levels in pregnancy is better than management based on only clinical findings in preventing seizures and avoiding complications in pregnancy. We obtained women's views on the two strategies.

Of the 560 mothers with epilepsy on medication, the drug levels fell in 267 women. The risk of seizures and pregnancy complications as well as infants' birthweight and mothers' quality of life were similar in the group managed by monitoring drug levels regularly and in the group managed based on only clinical findings. We did not identify a link between an increase in seizures and a decrease in drug levels. Babies born to mothers whose drug levels were monitored regularly were exposed to a higher dose of the drug at birth. Women reported that the decisions that they make regarding epilepsy medication intake and dose are influenced by their feelings of responsibility for the health of their babies.

Our findings do not support regular blood monitoring of antiepileptic drug levels in pregnancy.



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