## Oral morphine analgesia for preventing pain during invasive procedures in non-ventilated premature infants in hospital: the Poppi RCT

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# Plain English summary

### The Poppi RCT

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# **Plain English summary**

**B** abies cannot tell us if they are in pain, or how much pain they are in, which makes the measurement and treatment of infant pain difficult. Few clinical trials have tested whether or not different types of pain medication are effective and safe in babies. Premature babies are at risk of developing a condition called retinopathy of prematurity, which, if untreated, can cause blindness. Regular eye examinations are therefore vital. These examinations are thought to be painful, but the pain relief given is not fully effective. In this clinical trial, pain in babies was measured during an eye examination and during a clinically required blood test. A trial was run to test whether or not babies who were given morphine experienced less pain than those who received a placebo. In addition, whether or not morphine improved the stability of the babies' breathing and heartbeat was checked. It was planned to study 156 babies.

By November 2017, 31 babies were recruited to the trial. One baby was withdrawn, leaving 30 participants. Fifteen babies were given morphine and 15 babies were given the placebo solution. At this point, an independent committee looked at the data, and could see which babies had received morphine and which had placebo. The committee advised stopping the trial early, as morphine was having some side effects. The babies who had morphine had slower heart rates, slower breathing rates and more pauses in their breathing, and needed more increases in the oxygen they were given. There was no suggestion that morphine reduced pain more than did the placebo.

Oral morphine is not the right medicine for premature babies having eye examinations for retinopathy of prematurity. This finding will help guide neonatal units to develop their pain management practices. It is now planned to look at the effectiveness and safety of other medicines in babies.

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