Australian Placental Transfusion Study: echocardiography substudy

Thank you for participating in Australian Placental Transfusion Study (APTS).

The study is helping researchers answer the important health question of whether immediate or delayed cord clamping is better for premature newborn babies.

We appreciate the part played by our patient-volunteers. This contribution will improve the medical treatment of patients in the future. If you or your family have any questions about the results, please ask your study doctor or GP.

What was the trial about?

It has been standard practice to clamp the umbilical cord immediately at birth. This allows the professionals attending the birth to care for the baby and care for the mother separately. Care is especially important when babies are born premature.

Some studies have reported that waiting for a minute before clamping the cord sends more blood to the baby. This is called placental transfusion.

Placental transfusion is thought to work by increasing the blood flow in the baby's circulation. More blood flows to the brain and other organs, thus giving the baby a better start.

APTS is the largest trial designed to compare immediate and delayed cord clamping. APTS will find out whether delayed cord clamping prevents or reduces later disabilities that still affect some children born very early. These include brain injury, cerebral palsy, vision and hearing disabilities and infections.

The trial is currently recruiting 1600 mothers and babies.

One part of the study has been completed: the echocardiography substudy. It included a sample of 266 of the APTS babies. The main measurement of the APTS substudy was the blood flow returning to the heart during the first day of life. Half the babies had the cord clamped within 10 seconds of delivery. For the other half, the obstetrician or midwife waited for 60 seconds, holding the baby low, and then clamped the cord.

How was the effect of treatment measured?

The infants had echocardiography (heart ultrasound) three times: 3–6 hours, 6–12 hours, and 20–28 hours after birth. Each echocardiogram was read and assessed by a doctor who did not know the baby's identity or treatment. This was to make sure the assessments were not influenced if the doctor was in favour of one method or the other.

The main measurement was the flow of the blood going into the heart. It was measured at three time points, as mentioned earlier, and the lowest flow recorded was used for the comparison. The doctor measured various other indicators of the infant's circulation, including blood flow out of the heart. At the same times, other measurements of heart function and breathing were done.

Was the new treatment better?

The effect of delayed cord clamping on the babies' future welfare will not be known for some time.

In this substudy, outcomes were measured over the first day of life. The main measure, blood flow into the heart, was found to be similar in babies who had immediate and babies who had delayed cord clamping. There was no difference between the groups according to sex, weeks of gestation or whether it was a vaginal or caesarean birth.

Babies who had their cord clamped after a minute received more blood from the mother than those who had their cord clamped immediately. This was shown by the higher haemoglobin at birth and at 6 hours of age.

Blood flow out of the heart was less in the babies with delayed cord clamping. This was unexpected. There are several possible explanations, including that the hearts of babies who had their cord clamped later needed to pump less hard, as the blood had higher oxygen carrying capacity because of the higher haemoglobin.

What were the side-effects of the treatment?

Some infants had to be treated for various problems, as would be expected for those born very early. There were no particular harms related to the trial.

Were there any serious side-effects?

No unexpected serious adverse events were reported.

What does this mean for trial patients?

The differences in disability rates between immediate and delayed cord clamping will be reported after all 1600 infants have been followed up for approximately a year.

How will the results help patients and doctors in future?

The results of this blood flow study raise more questions about the two treatments.

Decisions about which is the better treatment will await the full results of the trial.

What will the researchers do next?

Preventing the complications of preterm birth is an important part of the CTC's research program.

Several large trials have begun in the past few years. They seek the best treatments for preterm infants during their time in intensive care to improve their long-term physical and psychological health.

Where can I find out more about the trial?

Talk with your trial doctor or nurse or your GP.

The results of this trial substudy have been published in a journal article:

Popat H, Robledo KP, Sebastian L, Evans N, Gill A, Kluckow M, Sinhal S, de Waal K, Tarnow-Mordi W, Osborn D. Effect of delayed cord clamping on systemic blood flow: a randomized controlled trial. *Journal of Pediatrics* 2016; volume 178: pages 81–86 and e82. Link to summary

Trial registration

www.anzctr.org.au

Registration number ACTRN12610000633088

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