

STUDY UPDATE FOR PARENTS: Australian Placental Transfusion Study

Thank you for taking part in the **Australian Placental Transfusion Study (APTS)**.

This is a summary of the results up until the babies in the study left hospital. It talks about the APTS study, as well as a summary of all the available evidence together. The results when all the babies have reached 2 years corrected age are still to come.

We greatly appreciate the contribution of all the APTS babies and their families. There were over 1600 babies from 25 hospitals in 7 countries who participated in this study. Your contribution has helped to improve medical treatment of premature babies in the future.

What was the trial about?

- Before APTS, it was standard practice to clamp the umbilical cord immediately at birth. This allowed doctors and nurses to care for the mother and the baby separately. Care is especially important when babies are born premature.
- Some studies had reported that waiting for 60 seconds before clamping the cord sends more blood to babies' brains and other organs – giving them a better start.
- APTS aimed to find out whether immediate cord clamping (clamping within 10 seconds of delivery) or delayed cord clamping (waiting at least 60 seconds before clamping) was better for premature babies in the short term and the long term.

What were the effects of the treatment?

The main measurement for this study was the number of babies who survived without major illness to 36 weeks post-menstrual age – close to the time a full-term baby is born. In this study, "major illness" included serious health conditions affecting babies' brains, eyes or intestines, and infections.

There was no difference between immediate and delayed clamping for the main measurement in APTS. However, the APTS study found that delayed clamping *might* reduce the number of premature babies who die before 36 weeks post-menstrual age.

The researchers have also reviewed all the relevant studies of delayed cord clamping in premature infants. When they analysed all these trials together, they found clear evidence that delayed clamping increased the number of babies who survived to leave hospital. They also found that delayed clamping is safe for mothers and premature infants.

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?

We will be following up with every family until their child is at least 2 years old. Only then will we know whether deferred cord clamping has a lasting benefit for premature babies.

Please stay in touch with your study hospital to complete the study follow-up.

How will the results help patients and doctors in future?

Without the research which you have made possible, we still would not know whether immediate or delayed cord clamping was better. Now, thanks to your support, more premature babies will survive in future.

That is an important step forward, but we need to know how babies with both immediate and delayed cord clamping are doing when they get older. It is very important for us to follow up the APTS study babies until they are at least two years of age to get the full picture.

Can these results explain why my baby had a particular outcome?

The difference in clamping time only explains part of the risks these tiny babies have. They cannot explain exactly why an individual baby had a particular outcome.

If you would like to discuss any part of the study further, please contact your local APTS investigator at the hospital where your baby was born, who will be happy to speak with you.

If my baby died or had a bad outcome, was I wrong to join the study?

No. Babies outside the study were at least as likely to have a bad outcome as those who took part. By joining the study, you have helped improve the outlook for other parents and babies.

One of my twins or triplets died and the other survived. Was I wrong to join the study?

No. Each twin or triplet had an equal chance of being allocated to the immediate or delayed cord clamping arm.

What will the researchers do next?

Preventing the complications of preterm birth is a very important area for research.

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?

Please speak with a specialist neonatal doctor at the hospital where your baby was cared for.

The APTS study and the systematic review of APTS and other studies are both being published in New England Journal of Medicine: www.nejm.org (APTS)

The American Journal of Obstetrics and Gynecology: www.ajog.org (Systematic review)

You can also find out more from the following websites:

- <https://www.ctc.usyd.edu.au/public-trial-pages/apts.aspx>
- <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=335752>

Thank you again for taking part in this important work.

APTS is funded by the National Health and Medical Council (Grant 571309) and sponsored by the University of Sydney. The authors have no financial relationships to disclose.