

# Studies confirm long-term safety of life-saving treatment for premature babies

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Hilary Jenkins (left) received repeat dose corticosteroids before her son, Connor, (right) was born at 27 weeks'. Credit: University of Auckland

More New Zealand families could benefit from a life-saving treatment for premature babies as new evidence from a major 10-year New

Zealand and Australian trial confirms its long-term safety.

The treatment involves injecting pregnant women at risk of giving birth before 35 weeks' with corticosteroids (different from muscle-building anabolic steroids). The steroids are synthetic versions of hormones normally released by the mother in late pregnancy. They flow through the placenta into the baby and speed up the development of her or his lungs, gut, cardiovascular and immune systems, which do not fully mature until after 36 weeks'.

Every year, around 5000 [babies](#) are born prematurely in New Zealand.

Babies whose mothers receive the steroids are less likely to die, less likely to have [breathing problems](#) and other serious health problems after birth, and any breathing problems tend to be less severe, compared to babies whose mothers do not have the treatment.

A single course of the steroids halves the risk of the most common lung illness in premature babies, called respiratory distress syndrome, from 40 percent to 21 percent in babies born before 32 weeks'.

About twice as many babies will benefit from the treatment when mothers who remain at risk of an early birth receive a repeat dose after seven days. The problem is, while single courses are routinely given to at-risk women, not all are given repeat doses due to lingering and – it is now clear - misplaced doubts about the long-term safety of this powerful drug.

To check for long-term effects, researchers from Liggins Institute at the University of Auckland, and from the University of Adelaide, have tracked into mid-childhood the health and development of 1000 babies whose mothers either received repeat doses of steroids or a placebo. The 10-year trial was called the Australasian Collaborative Trial of Repeat

## Doses of Corticosteroids (ACTORDS).

The latest study out of the trial, published today in top journal *Pediatrics*, found no difference in the bone health (mass) of children at age six to eight in the treatment and placebo groups.

The main study from the mid-childhood follow-up was published in *Pediatrics* last October. It showed no [adverse effects](#) on brain development and general health. An earlier study found no adverse effects on cardiovascular and metabolic (gut) health.

As well as showing the immediate benefits of repeat doses to babies, studies from the ACTORDS trial have found no differences in the survival rates, health, development and body size of children whose mothers had received repeat steroids and those who had not.

"Taken together, these results should completely reassure doctors about the short term benefits and long-term safety of repeat doses – meaning they can use antenatal corticosteroids to their fullest benefit," says Dr Chris McKinlay, a researcher at the Liggins Institute and neonatologist at Middlemore Hospital who was lead author on several of the papers.

"Concerns about the safety of repeat doses partly came from past animal studies that linked repeat doses with later adverse effects on the animal offspring," he says.

"But ACTORDS is the largest clinical trial of humans in the world to date with school-age follow-up, and it has clearly shown children born to mothers who were given repeat corticosteroids were no more likely to have health or development problems than those born to women who weren't given repeat doses."

The trial was led by Professor Caroline Crowther, also from the Liggins

Institute.

"It's been more than 40 years since New Zealand researchers Sir Mont Liggins – the Institute's namesake - and Ross Howie pioneered the use of corticosteroids," Professor Crowther says.

"The treatment has saved thousands of lives and dramatically improved the health outlook for many more [premature babies](#) around the world – but some families have missed out in the past due to a slow uptake."

Despite repeated studies confirming the benefits of a single course, it was years before this relatively inexpensive treatment become routine. (Another major Liggins Institute study led by Distinguished Professor Jane Harding, which involved tracking down babies from Liggins' and Howies' original trial 30 years later, helped finally turn opinion on the ground.)

Only last month, the Cochrane Collaboration, a global network of scientists that summarises medical evidence for doctors, updated its systematic review of evidence on the treatment, with two Institute experts, Dr Julie Brown and Dr Stuart Dalziel, on the author team.

Professor Crowther: "Back in the 1970s, Sir Mont and Dr Ross Howie suggested more doses where appropriate may be better, but this remained untested for 30 years - until the ACTORDS trial. Now we know, not only are they better, they are safe into mid childhood."

## Key points

- Corticosteroids (different from muscle-building anabolic steroids) are routinely given to pregnant women at risk of giving birth too early (before 35 weeks')
- The steroids quickly mature the baby's lungs and other organs

- Babies exposed to the steroids are less likely to die, less likely to have breathing problems and other serious health problems after birth, and their breathing problems tend to be less severe, compared to babies not exposed to the treatment
- About twice as many babies will benefit from the treatment when mothers who remain at risk of an early birth receive a repeat dose after seven days
- But not all mothers receive a repeat dose because of lingering but misplaced doubts about long-term safety
- Results from the international ACTORDS trial, led by Professor Caroline Crowther from the Liggins Institute, shows the long-term safety of this treatment
- Professor Crowther, co-researcher Dr Chris McKinlay (researcher at Liggins Institute and neonatologist at Middlemore Hospital) and their team hope this will finally lay to rest doubts and mean more mothers who could benefit from repeat doses receive them.

## Connor's story

West Auckland boy Connor Jenkins, 13, does well inside and outside the classroom.

"He's a social butterfly," says his mum, Hilary, a conveyancing practitioner. "He's a really smart kid, he always wants to be the best. You would never pick that he was such a small and early baby."

"Small" as in 850g (less than two pounds) when he was born at 27 weeks' gestation.

Hilary's water broke at 16 weeks', and as soon as Connor was big enough and beyond 26 weeks', her doctors gave her corticosteroids to grow his lungs and other body systems more quickly. When he still hadn't arrived

a week later, Hilary received a repeat dose of steroids, and joined ACTORDS, a major international trial designed to check the long-term safety of repeat doses.

While he was still in hospital, Connor developed an inguinal (groin) hernia – a common complication after premature birth. He had it operated on, then didn't wake up from the anaesthetic for three days.

"His lungs collapsed and he was on a big ventilator – that was very scary," says Hilary. "I think the steroids helped him, you only need a really little help sometimes to make a big difference."

As a trial participant, Connor received extra monitoring of his growth and development through to mid-childhood, which reassured his parents he was thriving in every respect.

Hilary and husband Stephan's firstborn Ryan had also been born early, at 32 weeks. But because there had been no warning, doctors did not get the chance to give Hilary corticosteroids.

Ryan, now 16, is "a very smart kid", but he has been diagnosed with Attention Deficit Disorder and has had some issues with his social development (common long-term complications from preterm birth).

"I really want other mothers to know that there are treatments that can help when it looks like you're going to have a premature baby," says Hilary. "It's a hugely scary time, so if you already know about things like the steroid treatment, and how repeat doses can help, you can feel reassured the doctors are doing everything they can to help you and your baby."

**More information:** Christopher J.D. McKinlay et al. Mid-Childhood Bone Mass After Exposure to Repeat Doses of Antenatal

Glucocorticoids: A Randomized Trial, *Pediatrics* (2017). [DOI: 10.1542/peds.2016-4250](https://doi.org/10.1542/peds.2016-4250)

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