



C*STEROID mum & baby - shared with consent

Can we safely reduce the risk of breathing problems for newborn babies by giving corticosteroid injections to their mothers before a planned caesarean section?

Welcome to newsletter one for the C*STEROID Trial

C*STEROID is a randomised controlled trial of **corticosteroids prior to planned caesarean section at 35+0 to 39+6 weeks**. Funded by the New Zealand Health Research Council and Australia's Medical Research Future Fund, this trial aims to recruit **2,500** mothers and their babies and will assess both potential benefit (respiratory) and any potential harms. The trial is designed with sufficient power to assess neonatal respiratory morbidity (benefit) and any potential harms such as neonatal hypoglycaemia to be able **to reliably inform future clinical practice**. The trial will also create a randomised cohort for longer term follow up in childhood.

The C*STEROID trial has been underway in Aotearoa New Zealand since October 2020 following completion of the C*STEROID Feasibility Study at National Women's Health, Auckland, Tauranga Hospital and Waikato Hospital (Jun 2019 - Mar 2020, results soon to be published). We are excited to welcome sites across New Zealand and all over Australia over the coming months!

Our lead investigators A/Professor Katie Groom based in NZ and A/Professor Joanne Said are available to support your hospital as you are ready to launch and we have a range of **recruitment resources (see page 2)** developed and refined over several years to support activity at your site!



Celebrating our 200th Auckland baby!

RECRUITMENT UPDATE

Site	Total (babies)	Last month
Auckland	207	8
Waikato	67	6
Tauranga	28	0
Christchurch	28	2
Wellington	14	0
Northland	3	0
Total	347	16

Australian sites coming soon!

C*STEROID Eligibility

Inclusion criteria

- Planned CS at 35⁺⁰ - 39⁺⁶ weeks
- ≥24 hours & <7 days until planned birth
- Singleton or twin pregnancy, live fetus

Exclusion criteria

- Diabetes
- Major fetal anomaly
- Prior im corticosteroid use in pregnancy
- Prior C*STEROID participation

What does C*STEROID involve?

- Invitation and consent
- Two 11.4mg betamethasone or saline placebo injections ≥24 hours and <7 days prior to planned CS, given 24 hours apart
- Neonatal blood glucose monitoring in the first 12 hours
- Questionnaires at study entry and 6 weeks after delivery

The remainder of clinical care continues as usual.



NEW RESEARCH FINDINGS

Reassuring new research findings on neonatal hypoglycaemia and childhood outcomes. **This research is highly relevant to C*STEROID as one of the co-primary outcomes of the C*STEROID Trial is neonatal hypoglycaemia.**



CHYLD

The New Zealand **CHYLD Study** which followed babies at-risk of hypoglycaemia has now completed follow up through to 9-10 years of age. The findings are reassuring. "Among participants at risk of neonatal hypoglycaemia who were screened and treated if needed, **exposure to neonatal hypoglycaemia compared with no such exposure was not significantly associated with lower educational achievement in mid-childhood.**"

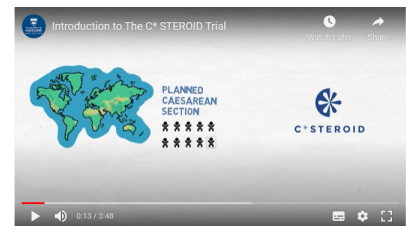
This is reassuring in the context of C*STEROID that even if babies are found to have hypoglycaemia and it is treated, this does not seem to have any associated developmental impacts later in life. JAMA. 2022;327(12):1158-1170. doi:10.1001/jama.2022.0992 For more info, visit: <https://www.auckland.ac.nz/en/news/2022/03/24/scientists-find-sweet-spot-for-at-risk-babies.html>

C*STEROID RESOURCES

Our goal is to make C*STEROID easily accessible to participants and trial processes as easy as possible for participating sites. Here are some of the resources available:

- **C*STEROID participant video** (under 4 mins)
- **Parent flyers** available in ten different languages. These are available at our study website and .pdf copies can be provided.
- A **Facebook page** where we share participant stories and updates. www.facebook.com/csteroidtrial
- **Clinician video** to help you explain the trial to potential participants (found on the info for clinicians and midwives tab).

www.liggins.auckland.ac.nz/csteroid



THANK YOU FOR YOUR ONGOING SUPPORT!

Thank you to all of our recruiting sites and sites in set up for making this trial possible.

Please continue to encourage all of your midwives and obstetricians to familiarise themselves with the C*STEROID Trial. We know that endorsement of the trial by a woman's own healthcare provider makes a big difference to participant engagement.

CONTACT US

A/Prof Katie Groom k.groom@auckland.ac.nz
C*STEROID Clinical Trial Manager
Ph: +64 22 4311 988 csteroid@auckland.ac.nz

[Australia](#)
A/Prof Joanne Said jsaid@unimelb.edu.au
Lee-anne Lynch lee-anne.Lynch@wh.org.au



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csteroid@auckland.ac.nz



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