

The C*STEROID Trial: Corticosteroids before planned caesarean section from 35+0 to 39+6 weeks of pregnancy.

ACTRN12620000914965

Status	RECRUITING
Phase	Phase 3
Sponsor	The University of Auckland
Enrollment	2,548 participants

Plain Language Summary

When babies are born by planned caesarean section, they miss out on the hormonal and physical changes that happen during labour — changes that help prepare the lungs for breathing. As a result, some babies born by planned caesarean have trouble breathing at birth and may need time in the neonatal unit for breathing support. Corticosteroid injections given to mothers before a premature birth are known to help babies' lungs mature, but it's not clear whether they also help for planned caesareans at or near full term (35 to 40 weeks).

The C*STEROID Trial is a large multi-centre, randomised, placebo-controlled study that will find out whether giving corticosteroid injections to mothers one to seven days before a planned caesarean section at 35 to nearly 40 weeks gestation reduces the risk of breathing problems in their babies. Researchers will also track longer-term child health outcomes to make sure the treatment is safe.

You may be eligible if you are pregnant with a singleton or twin pregnancy, your baby is alive, you are between 35 and nearly 40 weeks pregnant, and your caesarean is planned at least 24 hours but less than 7 days away. Women with diabetes (pre-existing or gestational) or a major fetal abnormality, or who have already received corticosteroid injections in this pregnancy, are not eligible.

Key Eligibility Criteria

Inclusion (3)

- Women for whom caesarean section is planned pre-labour at 35+0 to 39+6 weeks gestation.
- >24 hours and <7 days before planned birth.
- Singleton or twin pregnancy with a live fetus.

Exclusion (4)

- Diabetes: pre-existing or gestational.
- Major fetal abnormality.
- Prior corticosteroid use in this pregnancy (intramuscular corticosteroid use for fetal lung maturity).
- Prior enrolment in the C*STEROID Feasibility Study or C*STEROID Trial, in a previous pregnancy.

Locations (23 total)

Royal Hospital for Women - Randwick, NSW,QLD,SA,VIC, Australia
The Royal Women's Hospital - Parkville, NSW,QLD,SA,VIC, Australia
St George Hospital - Kogarah, NSW,QLD,SA,VIC, Australia
... and 20 more locations

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620000914965>

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