

Australasian Collaborative Trial of repeat doses of corticosteroids for the prevention of neonate respiratory disease

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| Submission date 18/03/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 17/06/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 04/06/2025 | Condition category Neonatal Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Australasian Collaborative Trial of repeat doses of corticosteroids for the prevention of neonate respiratory disease

Acronym

ACTORDS

Study objectives

Primary hypotheses:

Prenatal administration of repeat doses of corticosteroids at weekly intervals to women who remain at risk of preterm birth at less than 32 weeks gestation:

1. Reduces the risk of neonatal lung disease
2. Adversely affects fetal and neonatal measures of growth

Secondary hypothesis:

Prenatal administration of repeat doses of corticosteroids at weekly intervals to women who remain at risk of preterm birth at less than 32 weeks gestation increases the risk of maternal infection

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Neonate respiratory distress syndrome

Interventions

11.4 mg Celestone Chronodose or saline placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Celestone Chronodose

Primary outcome(s)

Neonatal respiratory outcomes:

1. Birthweight
2. Length and head circumference at birth
3. Primary discharge from hospital

Key secondary outcome(s)

On the mother:

1. Clinical chorioamnionitis requiring intrapartum antibiotics, maternal postpartum pyrexia greater than 38.0°C
2. Other measures of morbidity

On the infant:

Other measures of foetal and neonatal morbidity.

Completion date

31/12/2004

Eligibility

Key inclusion criteria

1. Women with a singleton, twin or triplet pregnancy
2. Gestational age less than 32 weeks who have received initial treatment of corticosteroid seven or more days ago
3. Responsible clinician considers her to be at continued risk of preterm birth
4. Informed, written signed consent
5. No contraindication to further corticosteroid therapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

982

Key exclusion criteria

1. Women with chorioamnionitis requiring urgent delivery
2. Women in whom the L/S ratio or equivalent test, if determined, is judged to be mature
3. Women who are in the second stage of labour
4. Women in whom corticosteroid therapy is considered essential
5. No contraindication to further corticosteroid therapy

Date of first enrolment

01/01/1998

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

Australia

Study participating centre

University of Adelaide

North Adelaide

Australia

5006

Sponsor information

Organisation

The University of Adelaide (Australia)

ROR

<https://ror.org/00892tw58>

Funder(s)

Funder type

Research council

Funder Name

National Health and Medical Research Council Project (Australia) (ref: 980185)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|----------------------|--------------|------------|----------------|-----------------|
| Results article | Twenty-year outcomes | 10/06/2006 | 04/06 | Yes | No |

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|------------------------------------|--|------------------|-----|----|
| Results article | | 28/05/2025 /2025 | Yes | No |
| Other publications | Outcomes in children at 2 years | 20/09/2007 | Yes | No |
| Other publications | Cardiovascular risk factors in children at 8 years | 27/10 /2022 | Yes | No |