

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

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

Date

Date

Peer

Patient-

Output type	Details	created	added	reviewed?	facing?
Results article		10/06/2006		Yes	No
Results article	Twenty-year outcomes	28/05/2025	04/06/2025	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