ISRCTN48656428 https://doi.org/10.1186/ISRCTN48656428

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

Submission date 18/03/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/06/2005	**Overall study status** Completed	
Last Edited 04/06/2025	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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 measure
Neonatal respiratory outcomes:
1. Birthweight
2. Length and head circumference at birth
3. Primary discharge from hospital

Secondary outcome measures
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.

Overall study start date
01/01/1998

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

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration.

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)

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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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		10/06/2006		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
Results article	Twenty-year outcomes	28/05/2025	04/06/2025	Yes	No