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Australasian Collaborative Trial of Vaginal Progesterone Therapy

Submission date 01/08/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/09/2005	**Overall study status** Completed	
Last Edited 18/12/2017	**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 Vaginal Progesterone Therapy

Study objectives
The primary hypothesis of this study is that the administration of progesterone to women considered at risk of preterm birth will reduce the risk of neonatal respiratory distress syndrome.

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)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Neonatal respiratory distress syndrome

Interventions
Eligible women will be randomised to either 100 mg vaginal progesterone or placebo treatment groups.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Progesterone

Primary outcome measure
Neonatal lung disease

Secondary outcome measures
1. Adverse outcomes for the woman
2. Maternal emotional wellbeing
3. Adverse outcomes for the infant
4. Costs of health care

Overall study start date
01/10/2005

Completion date
01/01/2009

Eligibility

Key inclusion criteria
Pregnant women with a history of prior spontaneous preterm birth at less than 34 weeks gestation.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
984

Key exclusion criteria
Women with preterm prelabour ruptured membranes, active labour (defined as the presence of uterine activity and cervical dilatation greater than 3 cm), known fetal anomaly, or any contraindication to progesterone therapy or to continuation of the pregnancy (e.g. chorioamnionitis requiring delivery).

Date of first enrolment
01/10/2005

Date of final enrolment
01/01/2009

Locations

Countries of recruitment
Australia

Study participating centre

University of Adelaide
Adelaide
Australia
5006

Sponsor information

Organisation
The University of Adelaide (Australia)

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Sponsor type
University/education

Website
http://www.adelaide.edu.au/

ROR
https://ror.org/00892tw58

Funder(s)

Funder type
Not defined

Funder Name
None to date. Application to National Health and Medical Research Council

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/02/2009		Yes	No
Results article	results	26/09/2017		Yes	No