

Australasian Collaborative Trial of Vaginal Progesterone Therapy

Submission date 01/08/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 19/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 18/12/2017	Condition category Neonatal Diseases	☐ 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 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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

Neonatal lung disease

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

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

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?
Results article	results	26/09/2017		Yes	No
Protocol article	protocol	24/02/2009		Yes	No