# Australasian Collaborative Trial of Vaginal Progesterone Therapy

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

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

Prof Caroline Crowther

#### Contact details

University of Adelaide Women's & Children's Hospital 72 King William Road Adelaide Australia 5006 +61 (0)8 8161 7647 caroline.crowther@adelaide.edu.au

## 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)

#### Sponsor details

North Terrace Adelaide Australia 5005 +61 (0)8 8161 7647 caroline.crowther@adelaide.edu.au

#### 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