# Trial of the effects of antenatal multiple courses of steroids versus a single course (TEAMS): pilot study

Recruitment status	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Pregnancy and Childbirth	<ul><li>Record updated in last year</li></ul>
	No longer recruiting  Overall study status  Completed  Condition category

#### Plain English summary of protocol

Not provided at time of registration

#### Study website

http://www.npeu.ox.ac.uk/teams/

# Contact information

# Type(s)

Scientific

#### Contact name

Ms Helen Adams

#### Contact details

TEAMS Administrator NPEU Institute of Health Sciences Old Road Headington Oxford United Kingdom OX3 7LF

# Additional identifiers

EudraCT/CTIS number

IRAS number

#### ClinicalTrials.gov number

# Secondary identifying numbers

SP3402

# Study information

#### Scientific Title

Trial of the effects of antenatal multiple courses of steroids versus a single course (TEAMS): pilot study

#### Acronym

**TEAMS** 

#### Study objectives

In women judged clinically to be at high risk of preterm delivery the policy of administering more than one course of antenatal corticosteroids does not reduce perinatal death, respiratory distress syndrome and intraventricular haemorrhage in neonates and has a long term adverse effect on later health and development when compared with a single course.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

The protocol was approved by the Multicentre Research Ethics Committee on 8th September 1999 (ref: 98/5/70)

# Study design

Randomised controlled trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Treatment

# Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

# Health condition(s) or problem(s) studied

Women at high risk of preterm delivery

#### **Interventions**

Women meeting the inclusion criteria and giving informed consent to participate in TEAMS will be randomised to receive either:

- 1. Two intramuscular injections of betamethasone
- 2. Placebo 12 24 hours apart

The number of courses depends on the risk of preterm delivery.

#### Intervention Type

Drug

#### Phase

Not Applicable

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

Steroids

#### Primary outcome measure

- 1. Neonatal death
- 2. Neurodevelopmental delay at age 2 years (corrected for gestational age at birth)

#### Secondary outcome measures

Short term outcomes:

- 1. Stillbirth
- 2. Death at any time before discharge from neonatal unit
- 3. Diagnosis of respiratory distress syndrome
- 4. Pneumothorax or other pulmonary airleak
- 5. Intraventricular haemorrhage confirmed by ultrasound
- 6. Diagnosis of necrotising enterocolitis
- 7. Chronic lung disease (oxygen dependency at 28 days of life)
- 8. Neonatal sepsis
- 9. Birthweight
- 10. Maternal sepsis

#### Long term outcomes:

- 1. Growth delay at age 2 (corrected)
- 2. Respiratory symptoms at age 2 years (corrected)
- 3. Sub-scale scores for the Vineland Adaptive Behaviour Scales and Bayley II Scales at age 2 years (corrected)
- 4. Readmission to hospital

#### Measures of health service utilisation:

- 1. Admission to, and duration of stay in, a neonatal intensive care unit
- 2. Use of, and length of time on, mechanical ventilation
- 3. Use of surfactant, postnatal corticosteroids, high frequency oscillation, nitric oxide and Extra Corporeal Membrane Oxygenation (ECMO)

#### Overall study start date

01/01/2000

#### Completion date

01/04/2003

# **Eligibility**

#### Key inclusion criteria

Women who have already received one course of antenatal steroids to improve foetal maturity and:

- 1. There is clinical uncertainty that a second course of steroids is indicated, and
- 2. Gestational age is less than 32 weeks

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

**Female** 

#### Target number of participants

600 women in approximately 50 centres

#### Key exclusion criteria

Maternal long-term systemic corticosteroid therapy (not including inhaled or topical therapy).

#### Date of first enrolment

01/01/2000

#### Date of final enrolment

01/04/2003

# Locations

#### Countries of recruitment

England

Italy

**United Kingdom** 

# Study participating centre Institute of Health Sciences

Oxford United Kingdom OX3 7LF

# Sponsor information

#### Organisation

Action Medical Research (UK)

#### Sponsor details

Vincent House Horsham West Sussex United Kingdom RH12 2DP

#### Sponsor type

Charity

#### Website

http://www.action.org.uk/

#### **ROR**

https://ror.org/01wcqa315

# Funder(s)

#### Funder type

Charity

#### **Funder Name**

Action Medical Research (UK)

#### Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Trusts, charities, foundations (both public and private)

#### Location

**United Kingdom** 

# **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