

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

<b>Submission date</b> 01/03/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/03/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/12/2014	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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)

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **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**

United Kingdom

England

Italy

**Study participating centre**

**Institute of Health Sciences**

Oxford

United Kingdom

OX3 7LF

## Sponsor information

**Organisation**

Action Medical Research (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

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes