ISRCTN46614711 https://doi.org/10.1186/ISRCTN46614711

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

Submission date 01/03/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 01/03/2001	**Overall study status** Completed	
Last Edited 11/12/2014	**Condition category** Pregnancy and Childbirth	

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes