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

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

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

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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)
actionmedres, action medical research for children, 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
Not provided at time of registration