

Prophylactic granulocyte-macrophage colony-stimulating factor (GM-CSF) to reduce sepsis in preterm neonates

Submission date 01/03/2001	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/03/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/04/2015	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.npeu.ox.ac.uk/programs>

Contact information

Type(s)

Scientific

Contact name

Dr Neena Modi

Contact details

Senior Lecturer/Consultant in Neonatal Paediatrics
Department of Paediatrics
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0NN
+44 (0)20 8383 3275
n.modi@ic.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SP3558

Study information

Scientific Title

Prophylactic granulocyte-macrophage colony-stimulating factor (GM-CSF) to reduce sepsis in preterm neonates: a randomised controlled trial

Acronym

PROGRAMS

Study objectives

To estimate the economic efficiency of administering prophylactic granulocytic-macrophage colony stimulating factor to preterm neonates at high risk of sepsis.

Please note that as of 21/01/2009 this record was updated. All update details can be found under the relevant field with the above update date.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS Executive South East MREC, 27/01/2000, ref: 99/85

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

Can be found at <http://www.npeu.ox.ac.uk/downloads/programs/PROGRAMS-PIL-v7.pdf>

Health condition(s) or problem(s) studied

Sepsis

Interventions

1. Once daily granulocyte-macrophage colony-stimulating factor (GM-CSF) 10 µg/kg by subcutaneous injection, commenced within 72 hours of birth and continued for 5 days
2. No GM-CSF therapy

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Granulocyte-macrophage colony-stimulating factor (GM-CSF)

Primary outcome measure

1. Sepsis-free survival at 14 days from trial entry
2. Economic evaluation outcome: incremental cost-effectiveness analysis

Secondary outcome measures

Added 21/01/2009:

1. Survival without moderate/severe disability at 2 years from term
2. Survival to discharge
3. Sepsis:
 - 3.1. Culture positive systemic infection, to 14 days from trial entry
 - 3.2. Culture negative systemic infection, to 14 days from trial entry
 - 3.3. Probable (culture positive or negative) systemic infection, to 28 days from trial entry
4. Clinical morbidity:
 - 4.1. Chronic lung disease (bronchopulmonary dysplasia)
 - 4.2. Necrotising enterocolitis, periventricular haemorrhage
 - 4.3. Periventricular leucomalacia and ventriculomegaly
5. Haematological:
 - 5.1. Culture positive systemic infection associated with neutropenia, to 14 days from trial entry
 - 5.2. Culture positive systemic infection associated with neutropenia, to 28 days from trial entry

Overall study start date

01/09/2001

Completion date

01/09/2005

Eligibility**Key inclusion criteria**

Babies are eligible for PROGRAMS if they are less than or equal to 31 completed weeks gestational age and small for gestational age (i.e. below 10th centile for birthweight) and within 72 hours of birth.

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

Added 21/01/2009: 320 participants

Key exclusion criteria

Added 21/01/2009:

1. Immediately life-threatening congenital abnormality
2. Evidence of early onset sepsis (maternal pyrexia greater than 38.0°C on two consecutive occasions during labour)

Date of first enrolment

01/09/2001

Date of final enrolment

01/09/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Hammersmith Hospital

London

United Kingdom

W12 0NN

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

Research Services, Medicine

Research Services Division

Faculty Building

South Kensington Campus

South Kensington

London

England
United Kingdom
SW7 2AZ

Sponsor type
University/education

Website
<http://www3.imperial.ac.uk/>

ROR
<https://ror.org/041kmwe10>

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

Funder Name
The Wellcome Trust (UK) (added 05/01/2010) (grant ref: 068499)

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?
Results article	results	17/01/2009		Yes	No
Results article	results	01/07/2015		Yes	No