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

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 01/03/2001 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 01/03/2001 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 30/04/2015 | Infections and Infestations | |

**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

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## 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 |