

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

<b>Submission date</b> 01/03/2001	<b>Recruitment status</b> No longer recruiting	<input checked="" 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> 30/04/2015	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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

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

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Neonate

### **Sex**

All

### **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

United Kingdom

England

## Study participating centre

**Hammersmith Hospital**

London

United Kingdom

W12 0NN

# Sponsor information

## Organisation

Imperial College London (UK)

## ROR

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

# 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

## Funder Name

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

# 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="#">Results article</a>	results	17/01/2009		Yes	No
<a href="#">Results article</a>	results	01/07/2015		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes