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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

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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