ISRCTN94984750 https://doi.org/10.1186/ISRCTN94984750

International Neonatal Immunotherapy Study

Submission date 25/10/2000	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 23/02/2021	**Condition category** 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
MRC ref: G9900825; ACTRN12606000273583

Study information

Scientific Title
International Neonatal Immunotherapy Study

Acronym
INIS

Study objectives

This trial tests the hypothesis that, in infants receiving antibiotics for clinical sepsis, the addition of non-specific, polyclonal intravenous immunoglobulin IgG (IVIG) therapy reduces mortality and major morbidity compared with antibiotics alone.

Protocol can be found at: https://www.npeu.ox.ac.uk/downloads/files/inis/INIS-Protocol.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Australia: Westmead Hospital Ethics Committee, 17/12/2001, ref: 2001/7/4.22 (1080)
All other centres obtained approval before participating in this trial.

Study design
Double-blind placebo-controlled randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obstetrics and Gynaecology

Interventions
Intravenous infusion of IVIG (500 mg [10 ml]/kg) or matching placebo, repeated after 48 h.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Intravenous immunoglobulin (IVIG)

Primary outcome(s)
Mortality or major disability at 2 years of age (corrected for gestational age at birth).

Key secondary outcome(s))
1. Short term: mortality, chronic lung disease or major cerebral abnormality before hospital discharge, significant positive culture after trial entry, pneumonia, necrotising enterocolitis, duration of respiratory support
2. Long term: mortality before two years, major disability at 2 years, non-major disability at 2 years.
3. Health service utilisation: length of hospital stay

Completion date
31/12/2008

Eligibility

Key inclusion criteria
Infants who:
1. Are receiving antibiotics with clinical evidence of definite or highly probable sepsis
2. There is substantial uncertainty that IVIG is indicated
3. Birth weight is less than 1500 g OR already has positive blood or Cerebral Spinal Fluid (CSF) culture OR receiving artificial ventilation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
IVIG already given or thought to be needed or contraindicated.

Date of first enrolment
01/06/2001

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
United Kingdom

England

Argentina

Australia

Belgium

Denmark

Greece

Ireland

New Zealand

Serbia

Study participating centre
National Perinatal Epidemiology Unit
Oxford
United Kingdom
OX3 7LF

Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Health and Medical Research Council (NHMRC) (Australia)

Alternative Name(s)

National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

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	29/09/2011		Yes	No
Protocol article	protocol	08/12/2008		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