

International Neonatal Immunotherapy Study

Submission date 25/10/2000	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 25/10/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 23/02/2021	Condition category Infections and Infestations	☐ 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

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.

Primary study design

Interventional

Study design

Double-blind placebo-controlled randomised controlled trial

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, Medical Research Committee and Advisory 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