

International Neonatal Immunotherapy Study

Submission date 25/10/2000	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/02/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.npeu.ox.ac.uk/inis>

Contact information

Type(s)

Scientific

Contact name

Dr Peter Brocklehurst

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Patient information can be found at: <https://www.npeu.ox.ac.uk/inis/leaflets>

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 measure

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

Secondary outcome measures

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

Overall study start date

01/06/2001

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

Age group

Neonate

Sex

Both

Target number of participants

5,000

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

Argentina

Australia

Belgium

Denmark

England

Greece

Ireland

New Zealand

Serbia

United Kingdom

Study participating centre

National Perinatal Epidemiology Unit

Oxford

United Kingdom

OX3 7LF

Sponsor information

Organisation

University of Oxford (UK)

Sponsor details

University Offices

Wellington Square

Oxford

England

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+44 (0)1865 270000

research.services@admin.ox.ac.uk

Sponsor type

University/education

Website

<http://www.ox.ac.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)

NHMRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Australia

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