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

Study website
http://www.npeu.ox.ac.uk/inis

Contact information

Type(s)
Scientific

Contact name
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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
United Kingdom
OX1 2JD
+44 (0)1865 270000
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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