

# International Neonatal Immunotherapy Study

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 23/02/2021	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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**Contact details**  
National Perinatal Epidemiology Unit  
Institute of Health Sciences  
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United Kingdom  
OX3 7LF

## 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, 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?
<a href="#">Results article</a>	results	29/09/2011		Yes	No
<a href="#">Protocol article</a>	protocol	08/12/2008		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes