

# To evaluate whether intravenous Adenosine would replace the need for inhaled nitric oxide (iNO) in the management of Persistent Pulmonary Hypertension of the Newborn (PPHN)

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/07/2009	<b>Condition category</b> Neonatal Diseases	<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**  
PICU  
Great Ormond Street Hospital  
Great Ormond Street  
London  
United Kingdom  
WC1N 3JH

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

## Secondary identifying numbers

N0012128264

# Study information

## Scientific Title

## Study objectives

Can Adenosine replace nitric oxide in the treatment of PPHN?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Neonatal Diseases: Persistent pulmonary hypertension

## Interventions

1. Intravenous adenosine
2. No adenosine

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Adenosine

**Primary outcome measure**

Whether Adenosine can replace or supplement the use of iNO in the treatment of PPHN.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/12/2002

**Completion date**

30/11/2003

## Eligibility

**Key inclusion criteria**

Neonates with PPHN requiring mechanical ventilation and inhaled nitric oxide at 20 parts per million

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Not Specified

**Target number of participants**

9

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/12/2002

**Date of final enrolment**

30/11/2003

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**PICU**  
London  
United Kingdom  
WC1N 3JH

## Sponsor information

**Organisation**  
Department of Health

**Sponsor details**  
Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

**Sponsor type**  
Government

**Website**  
<http://www.dh.gov.uk/Home/fs/en>

## Funder(s)

**Funder type**  
Hospital/treatment centre

**Funder Name**  
Great Ormond Street Hospital for Children NHS Trust (UK)

**Funder Name**  
Institute of Child Health (UK)

## 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?
<a href="#">Results article</a>	results	01/01/2004		Yes	No