

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)

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/07/2009	Condition category Neonatal Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

Not Specified

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

United Kingdom

England

Study participating centre

PICU

London

United Kingdom

WC1N 3JH

Sponsor information

Organisation

Department of Health

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

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?
Results article	results	01/01/2004		Yes	No