

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/07/2009	Condition category 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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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: Persistant 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?
Results article	results	01/01/2004		Yes	No