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Low dose inhaled nitric oxide in patients with acute lung injury

Submission date	Recruitment status
18/11/2011	No longer recruiting
Registration date	**Overall study status**
31/01/2012	Completed
Last Edited	**Condition category**
31/01/2012	Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Acute respiratory distress syndrome (ARDS) is a disease in which the lungs are inflamed, wet and there is difficulty transmitting oxygen from the air that enters the lung as part of the breathing process into the blood. It has many causes including infectious and non-infectious. The objectives of this study were to add a gas called nitric oxide(NO) to the air that participants were breathing in order to raise the oxygen level in the blood in hopes of improving outcome in participants with ARDS.

Who can participate?
Patients aged 18 and over, regardless of sex, who have ARDS and are on a breathing machine (called a ventilator) in order to enable oxygen transfer into the blood.

What does the study involve?
The study compared inhaled nitric oxide (INO) added to the air the patient was breathing though the machine with a placebo nitrogen, a safe gas that makes up most of the air that we breathe and would have no effect on ARDS. All participants will receive the same treatment that they would have received for ARDS, even if they had not participated in the study. If patients were randomly allocated to the group receiving inhaled nitric oxide, this would have been the additional therapy.

What are the possible benefits and risks of participating?
By participating it is possible that the subject will have improved oxygenation and that this may lead to improved outcome. There are no anticipated potential side effects of the treatment when delivered at the doses that will be used in this study.

Where is the study run from?
There were 35 centers taking part in this trial and the lead center is St. Johns Mercy Hospital St. Louis, Missouri.

When is study starting and how long is it expected to run for?
The start date of the study was 1996 and the duration of the study was approximately 3 years. Recruitment of participants was until late summer/fall 1999.

Who is funding the study?
The study was funded by INO Therapeutics (Now called IKARIA). They paid the costs associated with the trial.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
INOT06

Study information

Scientific Title
Low dose inhaled nitric oxide in patients with acute lung injury: a randomized controlled trial

Study objectives
To evaluate the clinical efficacy of low-dose (5-ppm) inhaled nitric oxide in patients with acute lung injury.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Subjects Committee (USA), 15 February 1996

Study design
Multicenter randomized blinded placebo-controlled

Primary study design

Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute lung injury

Interventions
Inhaled nitric oxide (5ppm) or placebo (nitrogen gas) is delivered with mechanical ventilator breaths until the patient is extubated or for a total of 28 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Nitric oxide

Primary outcome(s)
Days alive and off mechanical ventilation

Key secondary outcome(s))
Pulmonary function including spirometry, lung volumes and diffusion of carbon monoxide evaluated at 6 months

Completion date
08/09/1999

Eligibility

Key inclusion criteria
1. Mechanically ventilated patients with acute lung injury
2. Ratio of partial pressure of arterial oxygen (O2) to the fraction of inspired partial pressure of oxygen in arterial blood/fraction of inspired oxygen (Pa02/FiO2) ratio of 250 or less

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Sepsis as the cause of the acute lung injury

Date of first enrolment
27/03/1996

Date of final enrolment
08/09/1999

Locations

Countries of recruitment
United States of America

Study participating centre
Cooper University Hospital
Camden, New Jersey
United States of America
19102

Sponsor information

Organisation
Ohmeda/INO Therapeutics Inc (USA)

Funder(s)

Funder type
Industry

Funder Name
Ohmeda PPD/INO Therapeutics Inc. (USA)

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	07/04/2004		Yes	No