

# Nasal Intermittent Positive Pressure Ventilation

<b>Submission date</b> 28/08/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/08/2013	<b>Condition category</b> Pregnancy and Childbirth	<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

Dr Haresh Murli Kirpalani

### Contact details

Room 3N11F, McMaster University Medical Center  
1200 Main Street West  
Hamilton, Ontario  
Canada  
L8N 3Z5  
+1 905 521 2100 ext. 73024  
[kirpalan@mcmaster.ca](mailto:kirpalan@mcmaster.ca)

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00433212

Secondary identifying numbers

MCT-80246

## Study information

**Scientific Title**

Nasal ventilation in preterms (NIP) trial

**Acronym**

NIPPV

**Study objectives**

The use of nasal intermittent positive pressure ventilation (NIPPV) leads to a higher rate of survival without bronchopulmonary dysplasia than standard therapy with nasal continuous positive airways pressure (nCPAP).

As of 19/08/2009 this record has been updated to include an extended anticipated end date; the initial anticipated end date of your trial was 30th April 2009.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval was gained from Research Ethics Boards of:

1. Hamilton Health Sciences, Hamilton, Ontario, Canada on the 19th September 2006 (ref: #06-365)
2. Children's Hospital of Eastern Ontario, Ottawa, Ontario, Canada on the 11th January 2007 (ref: 06/30E)
3. Intermountain Healthcare (Institutional Review Board), Salt Lake City, Utah, USA on the 12th April 2007 (ref: # 06.2102)

Ethics approvals from other countries are pending.

**Study design**

Multicentre, international, randomised parallel, two arm placebo trial, with outcome assessor and data analyst blinded.

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Bronchopulmonary dysplasia

## **Interventions**

Experimental group: NIPPV as the sole non-ventilation respiratory support, until final weaning from all forms of respiratory support

Control group: nCPAP - nasal CPAP as the sole non-ventilation respiratory support, until final weaning from all forms of respiratory support.

Contact for public queries:

Dr. Brigitte Lemyre

Children's Hospital of Eastern Ontario (CHEO) (Canada)

401 Smyth Road

Ottawa, ON

Canada K1H 8L1

Phone: +1 613 737 8561

Fax: +1 613 737 8889

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome measure**

A composite primary outcome of survival to 36 weeks gestational age, free of moderate-severe bronchopulmonary dysplasia (BPD) (i.e. major event-free survival at 36 weeks gestational age). Following the US National Institutes for Child Health and Development (NIHCHD) Consensus Statement moderate-severe BPD is defined as requiring oxygen or any respiratory support at 36 weeks age. Formal assessment for the requirement of oxygen will be conducted using the oxygen reduction test developed by Walsh.

## **Secondary outcome measures**

1. All cause mortality at 36 weeks gestational age
2. All cause mortality before first discharge home
3. Bronchopulmonary dysplasia assessed at 36 weeks gestational age
4. Need for re-intubation by birth weight strata (less than 750 g; 750 g - 999 g)
5. Primary outcome per type and time of respiratory support at randomisation
6. Comparison of synchronised and non-synchronised NIPPV as a function of their effect on the primary outcome (survival at 36 weeks gestational age free of BPD)
7. Total duration of positive pressure respiratory support, i.e. mechanical ventilation plus either NIPPV or nCPAP, up to the time of discharge from the Neonatal Intensive Care Unit (NICU)
8. Total time on supplemental oxygen until discharge from NICU
9. Pulmonary air leaks identified radiologically by a masked paediatric radiologist - up to weaning off respiratory support
10. Nasal deformities: columella nasi necrosis or epistaxis
11. Intestinal perforation diagnosed by free gas in the peritoneal cavity on abdominal radiograph or at laparotomy
12. Necrotising enterocolitis, diagnosed at surgery, autopsy or by the radiographic findings of pneumatosis intestinalis or hepatobiliary gas (Bell stage II)
13. Time to establish full feeds (no longer requiring parenteral nutrition)
14. Weight gain - comparison at 36 weeks gestational age
15. Nosocomial infections, defined as positive blood culture, positive cerebrospinal fluid (CSF) culture and/or diagnosis of pneumonia

**Overall study start date**

01/09/2006

**Completion date**

31/12/2010

## **Eligibility**

**Key inclusion criteria**

Group A: complete obstetric and neonatal history and a clinical examination are required to confirm eligibility, however, results of study-specific laboratory or radiological investigations are not required to judge patient eligibility.

1. Gestational age at birth less than 30 weeks, either sex
2. Birthweight 999 grams or less
3. Intention to manage the infant with non-invasive respiratory support (i.e. no endotracheal tube), where either:

Group B: the infant is within the first 7 days of life and has never been intubated or has received less than 24 hours of total cumulative intubated respiratory support;

OR

Group B: the infant is within the first 28 days of life, has been managed with intubated respiratory support for 24 hours or more and is a candidate for extubation followed by non-invasive respiratory support.

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

1000

**Key exclusion criteria**

1. Life-threatening congenital abnormalities including congenital heart disease (excluding patent ductus arteriosus)
2. Infants known to require surgical treatment, e.g. congenital diaphragmatic hernia, tracheo-oesophageal fistula, omphalocele, gastroschisis
3. Abnormalities of the upper and lower airways such as Pierre-Robin sequence, Treacher-Collins syndrome, Goldenhar syndrome, cleft lips and palate
4. Neuromuscular disorders

**Date of first enrolment**

01/09/2006

**Date of final enrolment**

31/12/2010

# Locations

## Countries of recruitment

Australia

Canada

Germany

Singapore

Sweden

United Kingdom

United States of America

## Study participating centre

**Room 3N11F, McMaster University Medical Center**

Hamilton, Ontario

Canada

L8N 3Z5

# Sponsor information

## Organisation

McMaster University (Canada)

## Sponsor details

Department Clinical Epidemiology

c/o Ms Deborah Billings, Room HSC-2C4

1200 Main Street West

Hamilton, Ontario

Canada

L8N 3Z5

+1 905 525 9140 ext. 22665

billings@mcmaster.ca

## Sponsor type

University/education

## Website

<http://www.mcmaster.ca/>

## ROR

<https://ror.org/02fa3aq29>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr.irsc.gc.ca> (ref: MCT-80246)

# 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	15/08/2013		Yes	No