

# Randomised controlled trials and feasibility studies for newer modes of artificial ventilation in newborns with respiratory failure

<b>Submission date</b> 30/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/04/2011	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Sunil Sinha

**Contact details**  
Women & Children Division  
James Cook University Hospital  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW  
+44 (0)1642 854874  
s.k.sinha@ncl.ac.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0227097989

# Study information

## Scientific Title

### Study objectives

To assess the efficacy and safety of these newer modes of artificial ventilation, and assess their superiority over conventional ventilation in terms of mortality, analysis of cost of treatment, and short and long term respiratory outcome.

### 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

Respiratory failure

### Interventions

Randomised controlled trial of different modes of ventilation. Patients were randomised to different modes of ventilation, or the conventional ventilation methods.

### Intervention Type

Other

### Phase

Not Specified

### Primary outcome measure

Duration of ventilation and weaning

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/01/1999

**Completion date**

31/07/2004

## Eligibility

**Key inclusion criteria**

Babies less than 1500 g with respiratory distress syndrome (RDS) requiring ventilation

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Not Specified

**Target number of participants**

100

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/1999

**Date of final enrolment**

31/07/2004

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Women & Children Division

Middlesbrough

United Kingdom

TS4 3BW

# Sponsor information

## Organisation

Department of Health

## Sponsor details

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL  
+44 (0)20 7307 2622  
dhmail@doh.gsi.org.uk

## Sponsor type

Government

## Website

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

# Funder(s)

## Funder type

Government

## Funder Name

South Tees Hospitals NHS Trust (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	01/09/2006		Yes	No
<a href="#">Results article</a>	results	01/03/2007		Yes	No
<a href="#">Results article</a>	results	01/03/2009		Yes	No
<a href="#">Results article</a>	results	01/09/2009		Yes	No