

# Randomised trial of outpatient versus inpatient initiation on non-invasive ventilation (NIV) in adults and children with chronic ventilatory failure

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/10/2011	<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

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0201109246

# Study information

## Scientific Title

### Study objectives

Aim is to investigate whether starting NIV as an outpatient is as effective in terms of physiological improvement, tolerance and compliance, as standard inpatient initiation. We will also determine the cost and staffing implications of this change in clinical practice.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval was received from the local medical ethics committee before trial recruitment began.

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Not specified

### Study type(s)

Not Specified

## Participant information sheet

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

Respiratory: Chronic ventilatory failure

### Interventions

24 patients fulfilling entry criteria will be randomised to outpatient or inpatient initiation of NIV using a block randomisation process to ensure balance for diagnosis and age.

### Intervention Type

Other

### Phase

Not Specified

**Primary outcome measure**

Not provided at time of registration

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

13/02/2002

**Completion date**

31/12/2003

## Eligibility

**Key inclusion criteria**

24 patients per year.

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

24

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

13/02/2002

**Date of final enrolment**

31/12/2003

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Respiratory Medicine

London

United Kingdom  
SW3 6NP

## 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

Government

### Funder Name

Royal Brompton and Harefield 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	01/11/2008		Yes	No