

# A physiological evaluation of non invasive ventilation (NIV) during exercise in patients with chronic heart failure (CHF).

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/03/2016	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr D Schlosshan

### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N0436130405

# Study information

## Scientific Title

A physiological evaluation of non invasive ventilation (NIV) during exercise in patients with chronic heart failure (CHF).

## Study objectives

To examine the effects of non invasive ventilation (NIV) in patients with CHF on exercise capacity. This study aims to examine the effect of NIV on exercise capacity in patients with CHF, comparing NIV, sham NIV and no ventilatory support.

## 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

Chronic heart failure (CHF)

## Interventions

Randomised controlled trial to examine the effect of NIV on exercise capacity in patients with CHF, comparing NIV, sham NIV and no ventilatory support.

## Intervention Type

Other

## Phase

Not Specified

**Primary outcome measure**

Peak oxygen consumption in order to establish the effect of NIV on exercise capacity in patients with CHF.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/02/2002

**Completion date**

01/02/2004

**Eligibility****Key inclusion criteria**

Patients with New York Heart Association (NYHA) class 2 to 4 CHF

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Does not match inclusion criteria

**Date of first enrolment**

01/02/2002

**Date of final enrolment**

01/02/2004

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Leeds Teaching Hospitals NHS Trust**  
Respiratory Department  
Gledhow Wing  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

## 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

Leeds Teaching Hospitals NHS Trust

## 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