

# Randomised, placebo controlled study of the effect of sildenafil on hypoxia-induced pulmonary hypertension

<b>Submission date</b> 08/03/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/03/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/01/2011	<b>Condition category</b> Circulatory System	<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

**Protocol serial number**  
PG/02/024

## Study information

## Scientific Title

### Study objectives

Not provided at time of registration

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised placebo controlled study

### Primary study design

Interventional

### Study type(s)

Not Specified

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

Hypoxia-induced pulmonary hypertension

### Interventions

1. Placebo tds for 3 months
2. Sildenafil 25 mg tds for 3 months, or
3. Sildenafil 100 mg tds for 3 months

### Intervention Type

Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)

sildenafil

### Primary outcome(s)

Not provided at time of registration

### Key secondary outcome(s)

Not provided at time of registration

### Completion date

31/12/2001

## Eligibility

### Key inclusion criteria

1. Males or females aged 18 years and over
2. Resting pulmonary artery pressure  $\geq 25$  mmHg
3. Written informed consent must be obtained by the investigator before the subject is screened for the study

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Not provided at time of registration

**Date of first enrolment**

01/01/2001

**Date of final enrolment**

31/12/2001

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

United Kingdom

England

**Study participating centre**

Section on Clinical Pharmacology

London

United Kingdom

W12 0NN

**Sponsor information****Organisation**

British Heart Foundation (UK)

ROR

<https://ror.org/02wdwnk04>

## Funder(s)

**Funder type**

Charity

**Funder Name**

British Heart Foundation (UK)

**Alternative Name(s)**

the\_bhf, The British Heart Foundation, BHF

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Trusts, charities, foundations (both public and private)

**Location**

United Kingdom

## 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?
<a href="#">Results article</a>	results	24/07/2001		Yes	No