

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

Submission date 08/03/2002	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/03/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 06/01/2011	Condition category Circulatory System	☐ 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

Primary study design

Interventional

Study design

Randomised placebo controlled study

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 ≥ 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 British Heart Foundation, the_bhf, 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?
Results article	results	24/07/2001		Yes	No