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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/03/2002	**Overall study status** Completed	
Last Edited 06/01/2011	**Condition category** Circulatory System	

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
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

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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2001

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Section on Clinical Pharmacology
London
United Kingdom
W12 0NN

Sponsor information

Organisation
British Heart Foundation (UK)

Sponsor details
14 Fitzhardinge Street
London
United Kingdom
W1H 6DH
+44 (0)20 7935 0185
research@bhf.org.uk

Sponsor type
Charity

Website
http://www.bhf.org.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

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?
Results article	results	24/07/2001		Yes	No