

On demand prostacyclin inhalation in obstructive pulmonary disease and pulmonary hypertension

Submission date 06/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/11/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/02/2013	Condition category Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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
1.2

Study information

Scientific Title

On demand prostacyclin inhalation in obstructive pulmonary disease and pulmonary hypertension: a single centre prospective randomised double-blind crossover study

Acronym

The OPTION pilot study

Study objectives

We hypothesise that inhalative iloprost improves the exercise capacity in chronic obstructive pulmonary disease (COPD) patients with secondary pulmonary hypertension (PH).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Basel (Ethikkommission Beider Basel, Switzerland) approved on the 10th August 2009 (ref: EKBB 190/09)

Study design

Investigator driven single centre prospective randomised double-blind crossover study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD) with secondary pulmonary hypertension

Interventions

In every of the three study visits the patient will inhale one of the following in a randomised manner prior to the exercise test:

1. 0.9% saline (2 ml)
2. 10 µg iloprost diluted in 0.9% saline (2 ml)
3. 20 µg iloprost diluted in 0.9% saline (2 ml)

All study visits have to be done on different days within one month.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Iloprost

Primary outcome measure

Six-minute walking distance (6MWD) test, measured during the three study visits, after every inhalation.

Secondary outcome measures

Measured during the three study visits, after every inhalation:

1. Oxygen consumption
2. Oxygen saturation
3. Ventilation
4. Carbon dioxide production
5. Arterial oxygen content
6. Alveolar-arterial gradient
7. BORG score

Overall study start date

01/10/2009

Completion date

01/11/2010

Eligibility**Key inclusion criteria**

1. Patients with diagnosed COPD (Global initiative for chronic Obstructive Lung Disease [GOLD] I - IV)
2. Confirmed disproportional pulmonary arterial hypertension (mean pulmonary artery pressure of over 45 mmHg during exercise and/or over 30 mmHg at rest)
3. Aged above 40 years, men and women

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

17

Key exclusion criteria

1. Mental disorder preventing appropriate judgment concerning study participation
2. Significant comorbidity resulting in reduced life expectancy (lower than 6 months)
3. Significant exacerbation of COPD within the last month
4. Decompensated heart failure (left ventricular ejection fraction below 30%)
5. Present pulmonary embolism
6. PH explained by another cause than COPD
7. Pregnant and breastfeeding women

Date of first enrolment

01/10/2009

Date of final enrolment

01/11/2010

Locations

Countries of recruitment

Switzerland

Study participating centre

Petersgraben 4

Basel

Switzerland

4031

Sponsor information

Organisation

University Hospital Basel (Switzerland)

Sponsor details

Petersgraben 4

Basel

Switzerland

4031

Sponsor type

Hospital/treatment centre

Website

<http://www.unispital-basel.ch/>

ROR

<https://ror.org/04k51q396>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Basel (Switzerland)

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	01/04/2012		Yes	No