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On demand prostacyclin inhalation in obstructive pulmonary disease and pulmonary hypertension

Submission date	Recruitment status	[_] Prospectively registered
06/10/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/11/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/02/2013	Respiratory	

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
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

Study type(s)
Treatment

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel (Switzerland)

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	01/04/2012		Yes	No