

Comparison of two physiotherapy rehabilitation programmes on the exercise capacity in patients with severe pulmonary hypertension

Submission date 27/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/07/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/07/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Daiana Stolz

Contact details
University Hospital Basel
Pneumology
Petersgraben 4
Basel
Switzerland
4031

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EKBB 200/09

Study information

Scientific Title

Comparison of two physiotherapy rehabilitation programmes on the exercise capacity in patients with severe pulmonary hypertension: a randomised study

Acronym

Rehab PH

Study objectives

An endurance or/and resistance training improves the exercise capacity and quality of life of patients with severe pulmonary hypertension

Ethics approval required

Old ethics approval format

Ethics approval(s)

The local ethics committee, Basel, Switzerland approved in June 2009

Study design

Prospective randomised interventional trial

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 contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Pulmonary hypertension

Interventions

Intervention group 1: - endurance training: twice a week, 60 minutes, over 12 weeks

Intervention group 2: - resistance training: twice a week, 60 minutes, over 12 weeks

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Change in walking distance (6-minutes walk test) after 12 weeks of training and 12 weeks follow up

Secondary outcome measures

1. Change in VO2 submax (mobile spiroergometry) after 12 weeks of training and 12 weeks follow up
2. Change in scores for quality of life (SF-36 questionnaire) after 12 weeks of training and 12 weeks follow up
3. Change in scores (MRC-Dyspnoea scale) after 12 weeks of training and 12 weeks follow up
4. Change in daily activity measured with an accelerometer AiperMotion 320 after 12 weeks of training and 12 weeks follow up

Overall study start date

01/07/2010

Completion date

30/06/2012

Eligibility

Key inclusion criteria

1. Patients with pulmonary hypertension diagnosed by right heart catheterisation (mean pulmonary pressure [PAPm] > 25 mmHg)
2. New York Heart Association (NYHA) III - V
3. Walking distance (6-minutes walk test) > 150 meters
4. Patients with stable conditions on PH-related medication (single, double or triple therapy)
5. In stable condition for at least 3 months

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

36

Key exclusion criteria

1. Skeletal or muscular restrictions which make the training impossible
2. New occurrence of syncope
3. Concomitant neurological diseases
4. Patients with neoplastic diseases
5. Mental disability making a proper evaluation of the study impossible
6. Age > 18 years < 85
7. Rapid fatal disease

Date of first enrolment

01/07/2010

Date of final enrolment

30/06/2012

Locations

Countries of recruitment

Switzerland

Study participating centre

University Hospital Basel

Basel

Switzerland

4031

Sponsor information

Organisation

University Hospital Basel (Switzerland)

Sponsor details

University Hospital Basel

Pneumology

Petersgraben 4

Basel

Switzerland

4031

Sponsor type

University/education

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Basel (Switzerland) - Clinic of Pneumology and Respiratory Cell Research
(from research funds of Prof M Tamm)

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