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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/07/2010	**Overall study status** Completed	
Last Edited 15/07/2010	**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
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