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Swiss Study On Pulmonary Rehabilitation after Exacerbation

Submission date	Recruitment status	[_] Prospectively registered
06/09/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/10/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/03/2009	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.research-projects.unizh.ch/p7675.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
SOPRE

Study objectives
Early respiratory rehabilitation after acute exacerbation of Chronic Obstructive Pulmonary Disease (COPD) reduces exacerbations requiring medical treatment during an 18 months follow-up compared to respiratory rehabilitation in stable state after six months in patients with COPD Global initiative for chronic Obstructive Lung Disease (GOLD) stage II to IV and a history of repeated exacerbations.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Zurich REB (EK1286), St.Gallen REB (EKSG 06/071/1B), Schaffhausen REB (EK1286), ethics approval also received from the ethics committees of Lucerne, Bern and Thurgau.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease

Interventions
Respiratory rehabilitation with supervised physical exercise for 12 weeks and patient education program "Living well with COPD" (identical for both treatment arms).

Intervention Type

Other

Phase
Not Applicable

Primary outcome measure
Exacerbations requiring medical care (in- or outpatient).

Secondary outcome measures
1. Health-related quality of life (Chronic Respiratory Questionnaire and Feeling Thermometer)
2. Dyspnea (Medical Research Council scale)
3. Mortality
4. Costs

Overall study start date
11/09/2006

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Patients after in- or outpatient treatment of acute exacerbation of COPD defined as a sustained worsening over days to weeks of the patients symptoms from his or her usual stable state that is beyond normal day-to-day variations and the presence of at least two of the following symptoms:
1.1. Breathlessness
1.2. Cough
1.3. Increased sputum production, and
1.4. Change in sputum colour
2. At least two exacerbations in previous two years requiring in- or outpatient care
3. Within last three years, during stable phase, documented COPD with Gold stage II to IV
4. The patient is after in- or outpatient treatment in a medical condition that allows an immediate respiratory rehabilitation or recovery at home
5. More than 40 years of age

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
280

Key exclusion criteria

1. Hospitalisation for other reasons than acute exacerbation of COPD
2. Long term non-invasive ventilation (all but continuous positive airway pressure [CPAP], which is allowed)
3. Other lung diseases: Doctor diagnosed asthma and/or more than 20% reversibility of airflow obstruction after beta-2-mimetika during stable phase of COPD
4. Patients who cannot be randomised to usual care for medical reasons:
4.1. Impaired level of consciousness
4.2. Acute confusion
4.3. Acute changes on the radiograph or electrocardiogram
4.4. Arterial pH less than 7.35, or
4.5. Concomitant medical conditions
5. Orthopaedic, rheumatologic, cardiovascular or neurological disorders that inhibit exercise training, gymnastic or guided walking tours
6. Inability to follow patient education due to language (no German, French or Italian as communication language) or mental disorders (e.g. substance abuse, psychosis, dementia)

Date of first enrolment
11/09/2006

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Switzerland

Study participating centre
Horten Centre
Zurich
Switzerland
8091

Sponsor information

Organisation
University Hospital of Zurich (Switzerland)

Sponsor details
c/o Prof. E. Russi
Division of Pulmonary Medicine
Raemistrasse 100
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Sponsor type
Hospital/treatment centre

Website
http://www.unizh.ch/

ROR
https://ror.org/01462r250

Funder(s)

Funder type
Charity

Funder Name
Swiss Lung league (Switzerland)

Funder Name
Lung leagues of Swiss cantons (Switzerland)

Funder Name
Klinik Barmelweid (Switzerland)

Funder Name
Quadrimed (Switzerland)

Funder Name
Zurcher Hoehenklinik Wald (Zurich Elevator Hospitals Forest) (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	recruitment results	02/03/2009		Yes	No