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Interval exercise versus continuous exercise in patients with moderate to severe chronic obstructive pulmonary disease

Submission date 08/06/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 08/06/2004	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 20/10/2016	**Condition category** Respiratory	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic obstructive pulmonary disease is a disease of the lungs that is usually caused by smoking. In COPD, lung damage gradually worsens over time. People with COPD are short of breath and sometimes cough and wheeze. Symptoms slowly get worse over time, but most patients also have intermittent bouts of worsening of symptoms. Lung infections, cold weather, and exertion may bring on these bouts. In addition to medications, the treatment guidelines recommend high-intensity, continuous exercise to improve lung function. However, this type of exercise can be difficult for people with COPD to tolerate. Some believe that short intervals of exercise may also benefit patients with COPD and may be easier for them to accomplish. The aim of this study is to find out whether interval exercise produces the same benefits for people with COPD and is easier for them to tolerate than continuous exercise.

Who can participate?
Adult patients with COPD

What does the study involve?
Participants are randomly allocated to attend 12 to 15 supervised sessions of either continuous or intermittent high-intensity exercise over 3 weeks followed by unsupervised exercise at home. Participants used exercise bikes during the supervised exercise sessions. Participants allocated to continuous exercise warmed up for 2 minutes, pedaled at high intensity for 20 minutes (or until they needed to stop because of fatigue or other symptoms), and cooled down for 2 minutes. Participants in the intermittent exercise group warmed up for 2 minutes, pedaled for 20 minutes, alternating between 20 seconds at high intensity and 40 seconds at low intensity (or until they needed to stop because of fatigue or other symptoms), and cooled down for 2 minutes. Participants completed a standard questionnaire to assess their lung function at the start of the study and 5 weeks into the study. The researchers also collected information on the number of times participants had to take unplanned breaks during the supervised exercise sessions.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
AstraZeneca (Switzerland)

When is the study starting and how long is it expected to run for?
May 2004 to September 2005

Who is funding the study?
1. AstraZeneca (Switzerland)
2. The Helmut Horten Foundation

Who is the main contact?
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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

Interval exercise versus continuous exercise in patients with moderate to severe chronic obstructive pulmonary disease

Study objectives
The aim of this study is to assess if interval exercise compared to high intensity continuous exercise is not of inferior effectiveness in terms of health-related quality of life (HRQL) and exercise capacity improvements but associated with better exercise tolerance in patients with moderate to severe COPD at the beginning of a respiratory rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Kantonsspital Aarau, Aargau, Switzerland

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Group 1: 12-15 sessions of high intensity continuous exercise
Group 2: 12-15 sessions of interval exercise
Between group comparisons in terms of changes of clinical outcomes (health-related quality of life, functional exercise capacity and subjective patient experience of exercise) and physiological outcomes (exercise tests with gas exchange and ventilatory variables) during respiratory rehabilitation.

Intervention Type
Behavioural

Primary outcome measure
Health-related quality of life (HRQL), measured by the Chronic Respiratory Questionnaire (CRQ) two weeks after the end of rehabilitation

Secondary outcome measures
Secondary endpoints include additional clinical outcomes such as functional exercise capacity, other HRQL measures, patients' experience of physical exercise as well as physiological measures of the effects of physical exercise such as cardiopulmonary exercise testing.

Overall study start date
01/05/2004

Completion date
30/09/2005

Eligibility

Key inclusion criteria
COPD with Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage III and IV admitted to an inpatient respiratory rehabilitation

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2004

Date of final enrolment
30/09/2005

Locations

Countries of recruitment
Switzerland

Study participating centre

University of Zurich
Zurich
Switzerland
8091

Sponsor information

Organisation
AstraZeneca Switzerland

Sponsor details
Grafenau 10
Zug
Switzerland
6301

Sponsor type
Industry

ROR
https://ror.org/034rhks82

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Funder Name
Helmut Horten Foundation

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?
Protocol article	protocol	13/08/2004		Yes	No
Results article	results	05/12/2006		Yes	No