The efficacy of the walk-bike on quality of life and exercise capacity in patients with idiopathic pulmonary fibrosis: a pilot study.

Published: 03-04-2014
Last updated: 20-04-2024

Primary objective• To assess the effect of use of a walk-bike in IPF patients for 8 weeks on health-related quality of life, measured with the St. George Respiratory Questionnaire, at baseline, week 9 and week 18, in patients with IPF.Secondary…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Changes in physical activity
Study type	Interventional

Summary

ID

NL-OMON41589

Source
ToetsingOnline

Brief title
walk-bike IPF

Condition

- Changes in physical activity
- Lower respiratory tract disorders (excl obstruction and infection)
- Lifestyle issues

Synonym
lung fibrosis, scarring of the long

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: longfibrose patienten vereniging subsidie voor aanschaf materialen

Intervention

Keyword: exercise capacity, idiopathic pulmonary fibrosis, quality of life, walk-bike

Outcome measures

Primary outcome

Change in total score in health-related quality of life questionnaire SGRQ ,

measured at week 9 and week 18 compared to baseline.

Secondary outcome

Change in exercise capacity measures at week 9 and week 18 compared to baseline

(distance (m) during 6-minute-walk-test and average steps per day)

Change in score in health related quality of life questionnaires K-BILD abd

GAD-7 , measured at 9 and 18 weeks compared with baseline.

This questionnaire is self-administered.

Change in component scores (symptoms, activity and impact) in health-related

quality of life measured with SGRQ at week 9 and 18 compared to baseline.

Study description

Background summary

Background
Idiopathic Pulmonary Fibrosis (IPF) is a chronic, progressive and

life-threatening disease of unknown cause. The prevalence of IPF in the Netherlands is estimated to be 3200, with an incidence of 800-1600 a year. There is a male predominance and most patients are between 50 and 80 years of age. The median survival of IPF is 4 years.1 As the disease progresses, worsening of lung function and gas exchange impairment cause hypoxemia during physical activity leading to a downward spiral; dyspnea and fatigue lead to a reduction of daily physical activities, exercise tolerance, muscle strength and quality of life. Problems reported by IPF patients are social isolation, increased level of dependency and immobility.

Pharmacologic treatment options are limited. International studies showed that use of a new drug in patient with IPF gives a small reduction in pulmonary function decline. In these trials the effect on quality of life was not evaluated and international debate exists about the clinical relevance of these outcomes. In a selected, limited group of patients with IPF lung transplantation can be an option. The mean waiting time for lung transplantation in the Netherlands is 3 years and 33% of patients with IPF on the waiting list die before they get the chance to have a lung transplant.

In this devastating progressive disease with limited treatment options, treatments that could improve quality of life should be investigated more. Non-pharmacologic treatment like pulmonary rehabilitation programs is recommended by expert opinion for the majority of IPF patients to improve quality of life and exercise tolerance. A review on physical training in patients with different Interstitial Lung Disease including IPF indicates pulmonary rehabilitation has a beneficial effect on quality of life and functional exercise capacity in IPF patients. Often pulmonary rehabilitation programs are offered in outpatient clinics and specialized rehabilitation centers with a duration of 6 -12 weeks. Due to the limited life expectancy of IPF patients and practical problems with decreased mobility and transport, patients are often hesitant to participate in these external programs. Therefor appropriate alternative programs should be considered for these patients. Also the effect of these programs wanes when the program is discontinued.

A recent study demonstrated that a new-walking aid: the walk-bike or modern draisine, improved exercise performance in Chronic Obstructive Pulmonary Disease patients due to the more efficient way of moving without excessive metabolic demand. The effectiveness of the walk-bike in subjects with IPF is unknown. We hypothesize that use of this walk-bike in daily life extends the range and everyday mobility of IPF patients, thereby decreases the level of dependency and social isolation, factors that are associated with quality of life. If, with this low-cost intervention, daily activities of IPF patients increase, exercise capacity might improve too.

The objective of this pilot study is to assess the efficacy of the *walk-bike* on quality of life and exercise capacity in IPF patients.

Study objective

Primary objective
• To assess the effect of use of a walk-bike in IPF patients for 8 weeks on health-related quality of life, measured with the St. George Respiratory Questionnaire, at baseline, week 9 and week 18, in patients with IPF.

Secondary objectives
• To assess the change in measures of exercise capacity at 9 and 18 weeks compared to baseline (6MWT, daily physical activities).
• To assess the change on health-related quality of life measured with the questionnaires K-BILD and GAD-7 at week 9 and week 18 compared to baseline.

Study design

A randomized controlled crossover pilot study

Intervention

The intervention is use of a walk-bike in daily life during 8 weeks, with a minimum of 1 hour per day. The patient will be asked to record the time using the walk-bike in a diary. At baseline instructions will be given and a training under supervision.
The control group will receive standard treatment only.

Study burden and risks

Patients with IPF participating in this study might have personal benefit from participating in this study when using the walk-bike results in a better QoL. The burden is low, patients will be asked to use the walk-bike every-day with a minimum of one hour, register frequency and duration in a diary, to carry a small pedometer for 7 days at baseline, 8 weeks, 9 and 18 weeks (group that starts with intervention), or at baseline, 9, 17 and 18 weeks (group that starts in the control group) and to fill in questionnaires at baseline, 9 and 18 weeks. The use of the walk-bike has not been associated with an increased risk of falling or accidents in populations studied of the same age.
Use of the walk-bike is expected to change the quality of life and exercise performance in a positive way, without side effects. Treatment decisions will be at the discretion of the treating physician and not be influenced by the study. The outcome of the study may improve future care of patients with IPF.

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-IPF patients
-Diagnosis of IPF, including probable and possible diagnosis according to ATS/ERS criteria
-Written informed consent
-TLCOc >= 25% (pred) and FVC >= 50% (pred)
-6MWD >= 150 m
-Being clinically stable
-Absolute decline in TLCOc and FVC should be less than 10% in the past 6 months.

Exclusion criteria

-Participation in a formal rehabilitation program within 4 months of start of study
-Musculoskeletal disorders
-Severe cardiac diseases (ejection fraction < 30%, daily angina, or otherwise specified by treating cardiologist)
-Unable to understand informed consent

-Other conditions that hamper the use of a walk-bike

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-04-2014
Enrollment:	11
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-06-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-09-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	22513
CCMO	NL45411.078.14