The effect of post-thoracotomy pulmonary rehabilitation on quality of life.

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Primary:To evaluate the effects of a rehabilitation program on health related quality of life (SGRQ) in the 12 months postoperative period in patients with an elective thoracotomy.Secondary:To evaluate the effects of a rehabilitation program on...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON30490

Source
ToetsingOnline

Brief title
Post-thoracotomy rehabilitation and quality of life.

Condition

- Other condition
- Respiratory tract neoplasms
- Economic and housing issues

Synonym
Post-thoracotomy rehabilitation; lung-exercise program after thoraxsurgery.

Health condition

longrevalidatie

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: maatschap ongziekten en isala klinieken.

Intervention

Keyword: pain, quality of life, rehabilitation, thoracotomy

Outcome measures

Primary outcome

1. health related quality of life (SGRQ score).

Secondary outcome

1. general quality of life (SF-36).

2. acute / chronic post-thoracotomy pain (McGill and VAS).

3. impairment (changes in pulmonary function).

4. disability (exercise capacity; 6 Minute Walking Distance).

5. start to complete recovery (ECOG score of 0 or 1).

Study description

Background summary

Morbidity in the post operative phase of thoracotomies is characterised by pain, dyspnea, shoulder dysfunction and a loss of exercise tolerance may occur. There is literature about post-thoracotomy painsyndromes and postoperative quality of life has been investigated. However, data on post-thoracotomy rehabilitation and influence on morbidity and recovery are not available.

Study objective

Primary:

To evaluate the effects of a rehabilitation program on health related quality

of life (SGRQ) in the 12 months postoperative period in patients with an elective thoracotomy.

Secondary:

To evaluate the effects of a rehabilitation program on general quality of life (SF-36), acute / chronic postthoracotomy pain, impairment (changes in pulmonary function), disability (exercise capacity) and start to complete recovery (ECOG score of 0 or 1) 12 months postoperatively in patients with an elective thoracotomy.

Study design

Eighty-eight elective thoracotomy patients with an age between the 18 and 80 years will be recruited during two years. The follow up for each patient will be one year. The exclusion criteria are chronic pain involvement, a previous thoracotomy, comorbidity limiting rehabilitation, psychiatric illness and non-compliance.

Patients will be asked for participation before thoracotomy by informed consent and will be randomised post-thoracotomy, before discharge into a rehabilitation or 'regular care' group. Regular care is the regular approach after discharge; without a pulmonary rehabilitation program and with permission of regular physical therapy or when indicated (not related to thoracotomy). Regular sporting and exercises (no special training programs) will be tolerated. Randomisation will take place for rehabilitation or regular care by a minimisation program with special attendance to age (< 70 or >= 70 years), gender, the result of the 6 minute walk test (< 100 m or >= 100 m), the FEV1 (FEV1< 40% or >= FEV1 40 %) and type of surgery (pneumectomy vs other). During screening a spirometry and a 6 minute walk test will be performed. The first questionnaires (VAS, McGill pain questionnaire) will be given to the patients after enrolment and before thoracotomy. The SGRQ and the SF 36 will be given before, during and after rehabilitation.

The post-thoracotomy pain management consists of the standard analgetic treatment; a thoracic epidural catheter which will be slowly replaced by paracetamol, opioids and NSAID's. The consumption of analgetics will also be documented in the follow up. Supplementary oxygen and lung inhalation is given when necessary. This will be scored too. Regular physical therapy will be started directly after thoracotomy as soon as possible.

The rehabilitation program will be initiated within a month after discharge. The degree of the rehabilitation program will be separately detected for each patient by a cycle test (heart rate) within 3 weeks post-thoracotomy. Patients in the pulmonary rehabilitation program will be guided by a multidisciplinary team of pulmonologist, physical therapist and social worker during 12 weeks. The program will last 3 x 2 hours weekly consisting of exercise training and

education.

All patients will be followed up after discharge at 1 month, 3 months, 6 months and 12 months at the outpatient clinic of the pulmonology department and the pain clinic of the anaesthesia department. Before discharge and at these intervals (except for the SGRQ at 1 month), patients have to fill questionnaires about quality of life and pain (SF 36, SGRQ; McGill pain questionnaire and VAS). Exercise capacity by means of the 6 minutes walk test and spirometry will be measured after the accomplishment of the rehabilitation program at 3 months. Patients of the control group will also be asked during this visits whether they have had regular physical therapy or whether they are sporting to evaluate the exact effects of the rehabilitation program.

During follow up all the results between the experimental rehabilitation group and the regular care group will be compared. In the interpretation of these results start to complete recovery is defined as an ECOG score of 0 or 1.

Intervention

An early pulmonary rehabilitation program during 12 weeks (3x2 hours) initiated within a month after discharge from the hospital and will be guided by a multidisciplinary team consisting of pulmonologist, social worker and physical therapist.

Study burden and risks

Burden and risks associated with participation:

There are no adverse effects due to the rehabilitation program. Patients in the *regular care* group will not be guided by the multidisciplinary rehabilitation team.
The disadvantages are the following: Patients have to fill in quality of life questionnaires (SGRQ and SF-36), have to fill in pain questionnaires, have to evaluate a painscale at the pain clinic (VAS and McGill Pain questionnaire) and have to perform the 6 minutes walk-test and spirometry tests. Finally, patients have to visit the pulmonologist and the pain clinic more frequently.

The expected benefits are a faster recovery with a better exercise tolerance, less pain and a better quality of life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Elective thoracotomy patients.
2. Age >= 18 <= 80 years.
3. ECOG 0-2 post-thoracotomy.

Exclusion criteria

1. Patients with chronic pain.
2. A previous thoracotomy.
3. Comorbidity limiting rehabilitation:
- RA
- severe ischaemic heart disease or myocardial failure; EF <= 35 %.

- muscle diseases
- fibromyalgia
- neurological disorders (Parkinson, CVA and laesions of the spinal cord).
- psychiatric diseases
4. Non-compliance.

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2007
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2007
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
CCMO	NL14089.075.06