

Comparison of muscle sparing thoracotomy and posterolateral thoracotomy for pulmonary lobectomy for lung cancer

Submission date 08/10/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 20/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 17/08/2010	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Muscle sparing versus posterolateral thoracotomy for pulmonary lobectomy for lung cancer: a single centre randomised, double blind, controlled trial

Acronym

MST PLT

Study objectives

Muscle sparing thoracotomy should have more advantages in pain, muscle strength and pulmonary function than posterolateral thoracotomy.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committee (Comitato Etico Ospedale Maggiore di Milano I.R.C.C.S) approved on the 20th June 2003

Study design

Single centre prospective randomised controlled double blind trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lung cancer

Interventions

Patients are randomly divided in two groups in respect to surgical access to the thorax:

Group A: Posterolateral thoracotomy

Group B: Muscle-sparing thoracotomy

The duration of treatment is from 2 to 3 hours; the total duration of follow-up for all treatments are 3 years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Pain severity, assessed by patients 4 times a day in a relaxed position, and during coughing using a visual analogue pain scale (0 = no pain, 10 = most severe pain). The eight scores were then averaged to produce a daily composite score. Pain scores were measured pre-operatively and daily after surgery to post-operative day 7. After 1, 3, 6, 12 months and 3 years following the operation, patients were asked about the occurrence of symptoms of post-thoracotomy pain or post-thoracotomy syndrome.

2. Analgesic consumption for pain at the site of the thoracotomy was recorded. An aggregate

analgesic score (AAS) was computed adding 1 point for each mg of intravenous morphine used, 5 points for every dose of intravenous ketorolac (30 mg) and 4 points for each oral dose of acetaminophen-codeine (500/30 mg) administered.

Key secondary outcome(s)

1. Shoulder mobility and muscle strength was measured by a physiotherapist before surgery; the analyses were repeated at 1, 3 and 7 post-operative days and after 1 and 6 months by the same blinded observer. Muscle strength was recorded during adduction, abduction, flexion and extension on the operated side; the results were graded on a scale from 0 to 5 (5 = normal strength) according to the Daniels and Worthingham's muscle tests
2. Pulmonary function tests were obtained pre-operatively and daily after surgery to post-operative day 7. The spirometry was repeated at 1, 3, 6, 12 months and 3 years after the operation.
3. Major morbidity

Completion date

31/07/2006

Eligibility

Key inclusion criteria

1. Male and female
2. Aged greater than 18 and less than 80 years
3. Lung cancer (stage I and II)
4. Informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Previous thoracic surgery
2. Psychiatric disease
3. Non-controlled diabetes
4. Thoracic wall resection
5. Epidural analgesia
6. Severe cardiovascular or pulmonary disease
7. Drug abuse
8. Chronic pain syndromes

Date of first enrolment

01/07/2003

Date of final enrolment

31/07/2006

Locations

Countries of recruitment

Italy

Study participating centre

Via Francesco Sforza, 35

Milan

Italy

20122

Sponsor information

Organisation

Fondazione IRCCS Ospedale Maggiore Policlinico Mangiagalli Regina Elena (Italy)

ROR

<https://ror.org/016zn0y21>

Funder(s)

Funder type

Research organisation

Funder Name

Fondazione IRCCS Ospedale Maggiore Policlinico Mangiagalli Regina Elena (Italy)

Funder Name

University of Milan (Italy)

Results and Publications

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	results	01/10/2010		Yes	No