

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

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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure**

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.

**Secondary outcome measures**

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

**Overall study start date**

01/07/2003

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

100

**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

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20122

## **Sponsor information**

**Organisation**

Fondazione IRCCS Ospedale Maggiore Policlinico Mangiagalli Regina Elena (Italy)

**Sponsor details**

University of Milan

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**Sponsor type**

Research organisation

**Website**

<http://www.policlinico.mi.it>

**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

**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?
<a href="#">Results article</a>	results	01/10/2010		Yes	No