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

Submission date 08/10/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/10/2009	**Overall study status** Completed	
Last Edited 17/08/2010	**Condition category** Cancer	

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
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Sponsor information

Organisation
Fondazione IRCCS Ospedale Maggiore Policlinico Mangiagalli Regina Elena (Italy)

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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?
Results article	results	01/10/2010		Yes	No