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Chest Kinesio Taping for pain control after lung lobectomy

Submission date	Recruitment status	[_] Prospectively registered
24/11/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/12/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/05/2016	Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Pain relief is an important part of the care of patients who have undergone major thoracic (chest) surgery. Management of pain relief helps patients to actively perform respiratory (breathing) rehabilitation and to prevent pulmonary (lung) complications. A wide spectrum of medications and techniques for pain control is available, but the best strategy for pain management is still being debated. Kinesio Taping® is a rehabilitation method developed in the 1970s in Japan, and involves applying a specially designed drug-free elastic tape to the patient's skin. Pain control results from reducing local pressure by lifting the skin over the area of treatment. There are few studies exploring the use of Kinesio Taping in surgical patients. The aim of this study is to test the safety and effectiveness of Kinesio Taping in reducing chest pain after lung lobectomy (the removal of one lobe of the lung) to treat lung cancer.

Who can participate?
Patients undergoing lobectomy for lung cancer.

What does the study involve?
Patients are randomly allocated to be treated with either Kinesio Tape or the usual dressing tape. Tapes are applied by a specialized physiotherapist. Thoracic pain severity is self-assessed by all patients at 1, 2, 5, 8, 9 and 30 days after the operation.

What are the possible benefits and risks of participating?
The expected benefits for participants are reduction of chest pain after the operation, less need for pain relief, and shorter length of hospital stay. Local adverse events such as skin allergic reactions are the only potential risk of participating.

Where is the study run from?
The Center for Thoracic Surgery, University of Insubria (Italy)

When is the study starting and how long is it expected to run for?
January 2013 to December 2016

Who is funding the study?
Not provided at time of registration.

Who is the main contact?
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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
Chest Kinesio Taping® for pain control after lobectomy for lung cancer: a randomized controlled trial

Study objectives
Pain relief is a relevant component of the postoperative care of patients undergoing major thoracic surgery. Management of analgesia helps patients to actively perform respiratory rehabilitation and to prevent pulmonary complications. A wide spectrum of medications and techniques for pain control is available; however, the optimal strategy for postoperative pain management is still debated. Kinesio Taping® (KT) is a rehabilitation method developed in the 1970s in Japan, consisting of the application of a specially designed drug-free elastic tape to the

patient's skin, to achieve therapeutic effects. These include lymphatic, space, functional and mechanical corrections.
Pain control results from reduction of local pressure by lifting the skin over the area of treatment. According to Kase et al., space correction by KT reduces irritation of chemoceptors, improves the circulation of blood and lymph and helps exudate re-absorption, thus reducing pain. There are few studies exploring the use of KT in surgical patients.
We test the safety and efficacy of Kinesio Taping in reducing postoperative chest pain after lung lobectomy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Ospedale di Circolo Fondazione Macchi, 12/12/2012, No. 1216

Study design
Single-center single-blind randomized controlled 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
Postoperative chest pain after lung lobectomy

Interventions
Standard postoperative analgesia are administered in both groups (paracetamol/NSAID, epidural analgesia including opioids), with supplemental analgesia i.v. boluses at patient request. On postoperative day 1 in addition, a specialized physiotherapist applies KT near the chest wound to the experimental group patients, while usual dressing tapes mimicking KT are applied as placebo to controls.

Intervention Type
Other

Primary outcome measure
Thoracic pain severity score [visual analog scale (VAS) ranging 0–10] is self-assessed by all patients on postoperative day 1, 2, 5, 8, 9 and 30

Secondary outcome measures
1. Request for supplemental analgesia; method used to measure: categorical variable: yes if any supplemental analgesic (non-steroidal anti-inflammatory drugs (NSAID) and/or opioids) are administered at patient request, more than standard postoperative analgesia during the postoperative period (from day of surgery to the day of discharge from hospital); no if no supplemental analgesics are requested by the patient nor administered more than standard analgesia during the in-hospital postoperative period; timepoint: day of discharge from the hospital
2. Chest tube duration (days); timepoint: from day of surgery to the day of last chest tube removal
3. Morbidity; method used to measure: categorical variable: yes if any postoperative complication occurs during the postoperative period within 30 days from day of surgery; no if no postoperative complication occurs within 30 days from day of surgery; timepoint: 30th postoperative day from surgery
4. Post-operative length of stay (days); timepoint: from day of surgery to the day of discharge from hospital

Overall study start date
01/10/2012

Completion date
31/12/2016

Eligibility

Key inclusion criteria
Patients undergoing lung lobectomy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Age >85
2. Refusal
3. Previous exposure to Kinesio Taping
4. Recent trauma
5. Pre-existing pain or prolonged ICU treatment

Date of first enrolment
01/03/2013

Date of final enrolment
31/12/2016

Locations

Countries of recruitment
Italy

Study participating centre
University of Insubria
Center for Thoracic Surgery
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Sponsor information

Organisation
University of Insubria (Italy)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/00s409261

Funder(s)

Funder type
University/education

Funder Name

University of Insubria (Italy)

Results and Publications

Publication and dissemination plan

We plan to publish at least two manuscripts: one about methodology; one about the study results. In case of interest we plan an interim analysis publication on 31/12/2015. The final results will be published on 30/06/2017.

Intention to publish date

30/06/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2016		Yes	No