Optimal postoperative chest tube and pain management in patients surgically treated for primary spontaneous pneumothorax; a randomized controlled trial.

Published: 12-09-2023
Last updated: 19-08-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Thoracic disorders (excl lung and pleura)
Study type	Interventional

Summary

ID

NL-OMON56146

Source
ToetsingOnline

Brief title
Pneumotrial

Condition

- Thoracic disorders (excl lung and pleura)
- Respiratory tract therapeutic procedures

Synonym
Collapsed lung, Pneumothorax

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Medela (levert in Nederland de Thopaz drainage systemen, die in nagenoeg alle Nederlandse ziekenhuizen standaard gebruikt worden),Medela (levert in Nederland de Thopaz systemen)

Intervention

Keyword: Analgesia, Chest tube, Pleurodesis, Pneumothorax

Outcome measures

Primary outcome

This study encompasses two primary outcome measures:

1. Pain (non-inferiority): the proportion of NRS scores >=4, defined as the number of NRS scores >=4 divided by the total number of NRS measurements obtained during POD 0-3. A minimum of 11 NRS scores will be collected (1 at the recovery room and 10 afterwards on the Ward).

2. Length of stay (days): total number of in-hospital days including readmissions due to complications or recurrence within 30 days.

There is also a safety measure: absolute number of patients with recurrence with a maximum difference of 9 recurrences. Recurrence is defined as having an ipsilateral recurrent pneumothorax after chest tube removal, confirmed by X-ray or CT within 1-year, requiring reintervention (either tube thoracostomy or reoperation) or hospital readmission.

Secondary outcome

1. Quality of recovery (QoR) using the QoR-15 questionnaire at baseline, POD 0-3 and at 4 weeks' follow-up

2. Quality of life (QoL) using the EORTC QLQ-C30 at baseline and at 4 weeks, 3

months and 1 year postoperatively

3. Number of postoperative days having a urinary catheter

4. Postoperative morbidity during the first 30 days or first hospital admission, defined by the Clavien Dindo classification

5. Duration of postoperative chest tube drainage

6. Postoperative pain scores at rest and during mobilization/coughing during POD 0-3 and at 4 weeks, 3 months and 1 year follow-up

7. Cumulative use of postoperative additional analgesics and opioids during POD 0-3 and at 4 weeks follow-up

8. Daily degree of patient mobility (scale: in bed (1), in the chair (2), to the toilet (3), outside the patient*s hospital room (4)) during POD 0-3

9. Health status scored by the EQ-5D tool at baseline, POD 0-3, after 1 month, after 3 months and after 1 year follow-up

10. Patient satisfaction using the 5-point Likert scale during POD 0-3.

11. Cumulative use of additional chest X-rays and/or CT-scans (including reason)

12. Cost-effectiveness and cost-utility from a health care perspective using the Dutch Medical Consumption Questionnaire (DMCQ) and Productivity Cost Questionnaire (PCQ), adjusted to the study setting, at 4 weeks, 3 months and 1 year postoperatively.

Study description

Background summary

Primary spontaneous pneumothorax (PSP) generally occurs in young males with an incidence of 12.3 per 100,000 [Olesen 2019]. Guidelines recommend surgical pleurodesis through video-assisted thoracoscopic surgery (VATS) in case of recurrence after primarily conservative treatment [Henry 2003, Macduff 2010, Tschopp 2015]. Recommendations on duration of postoperative chest tube drainage and type of analgesia are however lacking. Historically, postoperative chest tubes are left in place for at least a fixed number of 3-5 days, irrespective of absence of air leakage. This period was deemed necessary for adequate pleurodesis and prevention of recurrence. Furuya however showed that chest tube removal on the same day of surgery is safe and associated with a reduced length of stay (LOS) [Furuya 2019]. Although thoracic epidural analgesia (TEA) is considered the gold standard for pain management after thoracic surgery, the use of VATS increases the interest in locoregional analgesia [Wildsmith 1989, Batchelor 2019]. The guideline on enhanced recovery after thoracic surgery suggests using locoregional analgesia to enhance mobilization and patient satisfaction, whereas the more recent PROSPECT guideline even recommends locoregional analgesia instead of TEA [Batchelor 2019, Feray 2022]. The arguments are that locoregional analgesia provides sufficient analgesia without epidural related side-effects, e.g. hypotension and urinary retention. Since studies on locoregional analgesia in PSP are scarce, we performed a retrospective study in Dutch hospitals to compare locoregional analgesia to TEA, confirming adequate pain control and earlier mobilization [Spaans submitted]. We furthermore performed a survey among Dutch thoracic surgeons showing variety in PSP management [van Steenwijk 2023]. Our survey shows that chest tubes are kept in place for a fixed number of days in 69% of respondents and TEA is used for analgesia in 78%. Our hypothesis is that a progressive policy with early chest tube removal and single-shot locoregional analgesia decrease LOS, improve quality of recovery and quality of life and is more cost-effective.

Study objective

Our objective is to compare the efficacy of early chest tube removal combined with single-shot PVB versus standard treatment (chest tube for at least 3 days and thoracic epidural analgesia (TEA)) after surgery for PSP. Efficacy is defined as proving safety regarding recurrence and non-inferiority regarding pain, and superiority regarding LOS.

Study design

An open-label, multicentre, four-arm randomized clinical trial using a 2x2 factorial design

Intervention

The Pneumotrial will study postoperative chest tube and pain management and

will encompass two interventions: 1. Early chest tube removal when the following postoperative criteria are met: patietn is lucid and capable of sitting up straight in bed, no air leakage for at least 4 hours or >=15mL/min during at least 6 hours, postoperative X-ray (at least 4 hours after surgery) demonstrating full lung expansion, absence of bloody drainage. 2. At the start of surgery, before pleurodesis, a single-shot PVB will be placed at 10 thoracic levels (T2-T11) with a total of 20mL local anesthetic in the paraertebral space under direct thoracoscopic vision.

Study burden and risks

The overall potential risks are considered low since the intervention strategies are already in use in some Dutch centres and have been demonstrated feasible and safe in single centre studies. The additional burden for the participants will be the completion of questionnaires. Regarding pain management it is realistic to expect that patients treated with the intervention single shot PVB will have more episodes of NRS >=4 and thus needing more morphine to control the pain.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with primary spontaneous pneumothorax (PSP) and referred for surgery due to recurrence, prolonged air leak (>=5 days), accompanied hemothorax or a profession at risk (diving, polar explorers, working with compressed air). - Age >= 16 years - Able to read and understand the Dutch language - Mentally able to provide informed consent - Patients should have a preoperative chest CT scan in order to exclude evident secondary pneumothorax. Previously made CT scans, within a time range of maximum 5 years, are accepted.

Exclusion criteria

- Previous ipsilateral thoracic surgery (except diagnostic thoracoscopy only) or ipsilateral thoracic radiotherapy
- Underlying lung disease that provoked the pneumothorax (secondary pneumothorax): genetically proven Birt-Hogg-Dubé syndrome, periodic pneumothorax in female patients in reproductive age with known endometriosis (or known catamenial pneumothorax), pulmonary cystic fibrosis, lungfibrosis, chronic obstructive pulmonary disease (COPD), active pneumonia, pulmonary ipsilateral malignancy
- Contra-indications for thoracic epidural analgesia (TEA) (infection at skin site, increased intracranial pressure, non-correctable coagulopathy, sepsis and mechanical spine obstruction)
- Patients chronically using opioids will be excluded since postoperative baseline opioid requirement will be higher and TEA remains the preferred technique for these patients
- Allergic reactions to analgesics used in the study

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2023
Enrollment:	340
Type:	Actual

Ethics review

Approved WMO Date:	12-09-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-10-2023
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	06-02-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	10-04-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-08-2024
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL84451.015.23