A prospective, randomised trial in pneumothorax therapy: manual aspiration versus conventional chest tube drainage.

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To evaluate the efficacy of manual aspiration in comparison to conventional chest tube drainage in pneumothorax therapy:1.whether the lung will expand by means of clinical and radiological findings.2.whether manual aspiration will shorten hospital...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Pleural disorders
Study type	Interventional

Summary

ID

NL-OMON30187

Source
ToetsingOnline

Brief title
pneumothorax therapy; manual aspiration versus usual care.

Condition

- Pleural disorders

Synonym
lung rupture, pneumothorax

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: maatschap longziekten.

Intervention

Keyword: comparison, drainage, manual aspiration, pneumothorax

Outcome measures

Primary outcome

1.The duration of LOS of each technique.

Secondary outcome

1.The success rate of each technique:

1. immediate: see below

2. two weeks: continous expansion

3. one year: no recurrence of the pneumothorax.

Conventional chest tube drainage; complete expansion of the lung, counteraction of the air leak and removal of the drain within 72 hours (immediate).

Manual aspiration: complete expansion and discharge within 24 hours (immediate).

Study description

Background summary

The aim of pneumothorax therapy is to restore lungexpansion and to prevent a pneumothorax in the future. Nowadays, conventional chest tube drainage is the standard therapy. Manual aspiration is as effective as the conventional drainage technique and has similar risks, according to a prior trial. However, a comparing trial in the Netherlands has never been performed. Benefits might be a shorter hospital stay with lower costs.

Study objective

To evaluate the efficacy of manual aspiration in comparison to conventional chest
tube drainage in pneumothorax therapy:

1.whether the lung will expand by means of clinical and radiological findings.
2.whether manual aspiration will shorten hospital admission.

Study design

prospective single-centre, open randomised trial.

Onehundredandfourteen patients with a first episode of a symptomatic pneumothorax admitted to the ER of the hospital or an asymptomatic pneumothorax with a size of >= 20 % as estimated by Light*s formula are recruited
and will be followed-up for one year, after they have given written informed consent. Exclusion criteria are a previous pneumothorax or lung fibrosis in medical history, pregnancy, comorbidity limiting decision making or a prior randomisation. Patients will be randomised by a computer minimisation program for the cause of pneumothorax (spontaneous or traumatic) the presence of smoking and gender and will undergo manual aspiration or conventional chest tube drainage:

Manual aspiration:
After skin desinfection and field preparation, an angio I.V. catheter with a diameter of 1.3 mm will be introduced in the second or third intercostal space midclavicular of the affected site after local anaesthesia (lidocaïne 1%).
In case of extreme obesity a pneumocatheter will be used. After fixation to the skin, the I.V. catheter will be connected with a three-way valve to a 50 ml syringe and air will be manually aspirated until a resistance is felt and no air is
acquired any longer. In case of success with an expanded lung at the chest X-ray,
the drainage system will be disconnected and patient will be observed during 24 hours. If manual drainage has failed, no second attempt will be made and

conventional drainage will be chosen. After the observation period a new chest X- ray will be made with a final evaluation. When the lung is still expanded at the
chest X-ray, discharge will follow. When no lung expansion is reached or in case of absorption of > 4000 ml air (prolonged air leak), conventional chest tube drainage will be performed.

Conventional chest tube drainage:

After skin desinfection and field preparation, a pneumocath catheter with a diameter of 2.7 mm will be introduced in the second or third intercostal space in the axillary line of the affected site after local anaesthesia (lidocaïne 1%).
The drain will be connected to a drainage system with a negative pressure of - 10 mmHg H2O. When airway leakage has ceased, expansion of the lung will be radiologically evaluated. The drain will be clipped for four hours. When the expansion of the lung still exists after four hours (chest X-ray), the drain will be
removed and patient will be discharged.

After discharge patients are seen at day 14 and after one year at the outpatient clinic with a chest X-ray to evaluate a possible recurrence of the pneumothorax.

Intervention

Conventional chest tube drainage:

After skin desinfection and field preparation, a pneumocath catheter with a diameter of 2,7 mm will be introduced in the second or third intercostal space in the axillary line of the affected site after local anaesthesia (lidocaïne 1%). The drain will be connected to a drainage system with a negative pressure of -10 mmHg H2O. When airway leakage has ceased, lungexpansion will be radiologically evaluated. The drain will be clipped for four hours. When the lungexpansion still exists after four hours, the drain will be removed.

Manual aspiration:

After skin desinfection and field preparation, an angio I.V. catheter with a diameter of 1,3 mm will be introduced in the second or third intercostal space midclaviculair of the affected site after local anaesthesia (lidocaïne 1%).
In case of extreme obesity a pneumocath catheter will be used. After fixation to the skin, the I.V. catheter will be connected with a three-way valve to a 50 ml
syringe and air will be manually aspirated until a resistance is felt and no

air is
acquired any longer. Expansion of the long will be confirmed radiologically whereafter the drainage system will be disconnected. Finally the patient will be observed during 24 hours and when the lung is still expanded at the chest X-ray, discharge will follow. When no lung expansion is reached or in case of absorption of > 4000 ml air (prolonged air leak), conventional chest tube drainage will be performed.

Study burden and risks

The risks of manual aspiration and chest tube drainage techniques are the same. Complications seem to be occur in only 1 % of the aspirations and they consist of haematothorax, retained catheter tips, subcutaneous emphysema and vasovagal reactions. The most important disadvantage is in case of an unsuccessfull treatment by manual aspiration with a still consisting pneumothorax. Patients in these situation have to undergo the conventional tube chest drainage at all. The benefit of the investigational approach might be that patients are discharged earlier from the hospital in case of success and it's costeffectiveness.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.patients with a first episode of a symptomatic pneumothorax admitted to the ER of the hospital (spontaneous or traumatic) or
2.patients with an asymptomatic pneumothorax with a size of >= 20 % as estimated by Light*s formula.
3.age >= 18 and < 85 years.
4.smoking is tolerated.

Exclusion criteria

1.re-pneumothorax
2.lung fibrosis
3.pregnant women
4.comorbidity limiting decision making (psychiatric disease, alcohol or drug abuse
5.COPD patients.
6.Marfan syndrome.
7.lung cancer patients.
8.tension pneumothorax.
9.prior randomisation

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2007
Enrollment:	114
Type:	Actual

Ethics review

Approved WMO

Date:	29-08-2006
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL13097.075.06