Dutch Pneumothorax Study

Published: 24-07-2012
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Primary objective:Investigate whether the use of a digital drainage system leads to a shorter hospital stay in patients with primary pneumothorax, in whom clinical drainage is indicated. Secondary objectives: To investigate whether the use of a...

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

Summary

ID

NL-OMON39210

Source
ToetsingOnline

Brief title
Dutch Pneumothorax Study

Condition

- Pleural disorders

Synonym
Pneumothorax

Research involving
Human

Sponsors and support

Primary sponsor: Kennemer Gasthuis
Source(s) of monetary or material Support: Het betreft hier een investigator initiated onderzoek

Intervention

Keyword: Pneumothorax, Thorax drainage

Outcome measures

Primary outcome

Length of hospital stay, measured in days. If a patient stays in the hospital longer than necessary for the treatment of the pneumothorax (e.g., because the patient waits for a place in a nursing home), the length of hospital stay is defined as length of drainage.

Secondary outcome

Description of the standard reference treatment. To describe the conservative treatment, we will measure whether suction is applied and why, whether provocative clamping is performed, how many chest X-rays are made during treatment, and whether (and when) pleurodesis and surgery are performed.

Study description

Background summary

Treatment of the pneumothorax has two goals: removal of pleural air (leading to expansion of the lung) and pleurodesis. Different treatment options are available: a *wait and see* policy, manual aspiration, drainage, thoracoscopy or surgery. Guidelines for treatment vary among different countries.
Until now, there have not been any clinical trials performed with digital drainage in the treatment of primary pneumothorax. In postoperative patients, digital drainage has shown reduction in hospital stay when compared to analogue drainage. We hypothesize that digital drainage system leads to shorter hospital stay in patients with primary pneumothorax.

Study objective

Primary objective:
Investigate whether the use of a digital drainage system leads to a shorter hospital stay in patients with primary pneumothorax, in whom clinical drainage is indicated.
Secondary objectives:

To investigate whether the use of a digital drainage system leads to a difference in treatment failure, defined as a recurrence in pneumothorax within twelve weeks after chest tube removal, leading to a aspiration, drainage, thoracoscopy or surgery.

Study design

This is a multi-center, randomized trial. There is no blinding due to the nature of the study. The trial will take place in 9 Dutch hospitals, mostly training centers for pulmonologists. 190 Patients in both groups will be collected within 2 years. Patients will randomly be assigned to analogue and digital drainage.

Intervention

None.

Study burden and risks

Not applicable.

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

- Pneumothorax with need for clinical drainage.
- Age >=18 years of age at the time of signature of the informed consent form.
- Able to sign informed consent.
- In the view of the investigator, the patient can and will comply with the requirements of the protocol.

Exclusion criteria

- Respiratory failure, defined as need for positive pressure ventilation.
- Uncontrolled bleeding tendency.
- Need for treatment in intensive care unit.

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:	Recruitment stopped
Start date (anticipated):	29-10-2012
Enrollment:	190

Type:	Actual

Ethics review

Approved WMO Date:	24-07-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21901
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL36778.018.11
OMON	NL-OMON21901