De Nederlandse Pneumothorax Studie

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21901

Source
Nationaal Trial Register

Brief title
DPS

Health condition

Primary spontaneous pneumothorax
(primaire spontane pneumothorax)
Drainage system (drainage systeem), digital versus analogue (digitaal vs analoog)

Sponsors and support

Primary sponsor: Performer: Kennemer Gasthuis Haarlem
(investigator-initiated study)

Intervention

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

- 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 randomization, leading to a aspiration, drainage, thoracoscopy or surgery.

Study description

Background summary

N/A

Study objective

Digital drainage systems lead to shorter hospital stay in patients with primary pneumothorax.

Study design

Day 0 = inclusion, randomisation
Days 0-x = hospital stay
Week 4 = visit outpatient clinic
Week 12 = follow-up by phone

Intervention

Patients are randomized to receive a digital drainage system versus an analogue drainage system

Contacts

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Eligibility criteria

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-10-2012
Enrollment:	190
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-09-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39210
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4022
NTR-old	NTR4195
CCMO	NL36778.018.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39210

Study results

Summary results
N/A