

Shortening the lenght of stay in patients with pneumothorax by pleurodesis with autologous blood.

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Pleurodesis with autologous blood may result in shorter length of stay of inpatients who have a chest tube. This study is designed to evaluate its significance in pneumothorax patients.

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

Summary

ID

NL-OMON30504

Source

ToetsingOnline

Brief title

Autologous blood-patch pleurodesis.

Condition

- Pleural disorders

Synonym

collapsed lung, pneumothorax

Research involving

Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar

Source(s) of monetary or material Support: geen financiering

Intervention

Keyword: Autologous blood, Pleurodesis, Pneumothorax, PSP

Outcome measures

Primary outcome

Shorten length of stay

Secondary outcome

duration of air leak

duration of drainage

complications

fever till 72 hours after pleurodesis

fever after 72 hours after pleurodesis

empyema

positive culture of pleural fluid

need to surgical intervention due to persistance of air lek (VATS, thoracotomy)

recurrence rate within one month and after one year

Study description

Background summary

Pneumothorax is relatively common, most of the patients should have a chest tube for a period of at least a few days. Pleurodesis with autologous blood may shorten the length of stay. There are a few non-randomised, relatively small studies confirming this hypothesis as it was proven to be a highly effective and safe procedure.

Study objective

Pleurodesis with autologous blood may result in shorter length of stay of inpatients who have a chest tube. This study is designed to evaluate its

significance in pneumothorax patients.

Study design

After insertion of a chest tube the patients are observed for air leak. If there are air leak after 24 - 36 hours the patient may be included if he is eligible and signs the informed consent. The patients are randomised and included in two groups, one study group and one control group. The patients in study group would have pleurodesis with 100 ml autologous blood. Thereafter is management of the patient in both groups are the same and contains the standard pneumothorax management with chest tube.

Intervention

After insertion of chest tube:

- Patients in the study group: if after 24 - 36 hours still air leak, pleurodesis with 100 ml autologous blood.
- Control group: observation only

Study burden and risks

Pleurodesis with autologous blood is painless and without other discomfort. Blood taken from a vein is not associated with much discomfort. The procedure is very safe and the incidence of adverse events is reported to be very low.

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

eligible for the study, need to have tube insertion, air leak > 24 hours after thorax drian is inserted

Exclusion criteria

post-operative pneumothorax, signs of bacteremia, pneumothorax as a result of multitrauma, recurrent pneumothorax

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date: 10-07-2007

Application type: First submission

Review commission: METC Noord-Holland (Alkmaar)

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	NL15660.094.07