The Role of Clamping Before Removal of a Pneumothorax Drain Connected to a Digital Drainage System

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To demonstrate that removal of drains exclusively based on digital drainage system data is non-inferior to additional clamping trials regarding recurrent pneumothorax requiring chest tube reinsertion.

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

Summary

ID

NL-OMON51368

Source
ToetsingOnline

Brief title
The Clamping Trial

Condition

- Pleural disorders

Synonym
Collapsed lung, pneumothorax

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Isala Klinieken

Intervention

Keyword: Airleak, Chest tube, Digital drainage system, Pneumothorax

Outcome measures

Primary outcome

Primary outcome measure: recurrent pneumothorax after chest tube removal requiring chest tube reinsertion.

Secondary outcome

Secondary outcome measures: hospital length of stay, recurrent intervention, number of additional imaging studies, and pneumothorax or subcutaneous emphysema; not requiring chest tube reinsertion.

Study description

Background summary

Determining and timing of chest tube removal has been a continuous topic of debate amongst both surgeons and pulmonologist. It is plausible that provocative clamping tests are no longer necessary when a digital continuous recording drainage device is used that demonstrates the absence of (intermittent) air leak. However, clamping trials are still performed in clinical care, it is an expert opinion*s policy prompted by fear of recurrent pneumothorax and no comparative studies exist. We hypothesize that chest tube removal exclusively based on digital drainage system data is as safe as adding a clamping test before removal in patients treated for pneumothorax or after lung surgery.

Study objective

To demonstrate that removal of drains exclusively based on digital drainage system data is non-inferior to additional clamping trials regarding recurrent pneumothorax requiring chest tube reinsertion.

Study design

The study will be conducted as a, prospective, open label, non-inferiority,

randomized controlled trial.

Intervention

In the intervention group; chest tube removal will be determined by air flow criteria as indicated by the digital drainage system data. In the control group removal will be determined by the same criteria of the digital drainage system but before removal, a chest tube clamping test will be performed.

Study burden and risks

Procedures as described for the study groups are both used in clinical care, therefore the risks and burden associated with participation is comparable to the standard of care. Digital drainage systems result in less complications after chest tube removal than analogue drainage systems. Clamping trials, although having small but implicit risk of tension pneumothorax, leave the possibility to open the air drain immediately by removing the clamps. Removing the drain based on digital leakage data might shorten drainage time but requires a new drain when the lung collapses with symptoms. As both courses are used in clinical practice, clarity about the optimal approach is desirable and justifies a prospective randomised trial. Possible benefit will be shorter chest tube duration.

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

- Digital chest tube drainage system
- Pneumothorax (primary, secondary, pulmonary surgery)

Exclusion criteria

• Pleural effusion as primary indication for chest tube placement.
• Empyema
• Suspected chest tube malfunction (e.g., leaking, occlusion, malposition)
• Intubated during chest tube removal

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):	16-09-2022
Enrollment:	106
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2022
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
ClinicalTrials.gov	NCT05180955
CCMO	NL81018.075.22