# Cryo- vs Surgical Lung biopsy for diagnosing interstitial lung disease: a randomized controlled trial

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1. To compare the need for (prolonged) chest tube drainage in two different diagnostic strategies to acquire lung tissue in ILD (bronchoscopic cryobiopsy followed on indication by surgical lung biopsy (intervention) versus immediate surgical lung...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Interventional

## Summary

### ID

NL-OMON48733

**Source** ToetsingOnline

Brief title The COLD study

## Condition

• Lower respiratory tract disorders (excl obstruction and infection)

#### Synonym

diffuse parenchymal lung diseases, interstitial lung disease

### **Research involving**

Human

## **Sponsors and support**

Primary sponsor: Academisch Medisch Centrum Source(s) of monetary or material Support: ZonMW

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### Intervention

**Keyword:** Cryobiopsy, Endobronchial interventions, Interstitial lung disease, Surgical lung biopsy

### **Outcome measures**

#### **Primary outcome**

(prolonged) need for chest tube drainage

#### Secondary outcome

complications, comprehensive complication index, in hospital stay, days with

chest tube, pain and pain medication use, health related quality of life,

diagnostic yield and diagnostic confidence per diagnostic strategy and

procedure, patient preference and health care costs.

## **Study description**

#### **Background summary**

Assessing an accurate diagnosis of interstitial lung disease (ILD) can be challenging. In case of a need for tissue verification following HRCT, surgical lung biopsy (SLB) is indicated. Diagnostic yield of SLB is high (>90%) however, invasive and associated with significant morbidity, complications and health care utilisation. Transbronchial cryobiopsy (TBCB) is a recently developed bronchoscopic procedure; its diagnostic yield is lower (75%), but TBCB might be an attractive first step diagnostic approach for being considerably less invasive than SLB. Due to the absence of prospective studies between TBCB and SLB the optimal diagnostic strategy for tissue acquisition in ILD is currently unknown.

#### **Study objective**

1. To compare the need for (prolonged) chest tube drainage in two different diagnostic strategies to acquire lung tissue in ILD (bronchoscopic cryobiopsy followed on indication by surgical lung biopsy (intervention) versus immediate surgical lung biopsy (current standard))

2. To register and describe adverse events associated with the two different diagnostic strategies to acquire lung tissue in ILD in surgical candidates; 3.

To asses compare patient- and healthcare burden of the two different diagnostic strategies for tissue acquisition in ILD patients;

4. To asses complications, patient- and healthcare burden among patients who are unfit to undergo surgical lung biopsy and receive cryobiopsy instead.

#### Study design

Randomized controlled trial

#### Intervention

Randomization between transbronchial cryobiopsy (followed by surgical biopsy in case of inconclusive results) versus immediate surgical biopsy.

#### Study burden and risks

Participants will be asked to complete EQ-5D-5L questionnaires and VAS pain questionnaires at regular intervals during follow-up and iMCQ and iPCQ questionnaires adjusted to the study setting at the end of follow-up. In the diagnostic strategy with step up approach it is to be expected that in 3 out of 4 participants a surgical procedure will be prevented, as a diagnosis is provided by TBCB. However, participants with inconclusive TBCB results will have to undergo a subsequent surgical lung biopsy.

## 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**

interstitial lung disease based on HR-CT scan and a ILD-multidisciplinary discussion panel decides there is a need for lungbiopsy.

### **Exclusion criteria**

Inability and willingness to provide informed consent, Inability to comply with study protocol, Use of carbasalate calcium, clopidogrel, or other new anti-platelet therapy that cannot be stopped temporarily, Thrombocytopenia <  $50x10^9/L$ , Pregnancy, History of pulmonary hypertension (systolic pulmonary artery pressure > 50 mmHg), Diffusing capacity < 30%, Forced vital capacity <50% \* Forced expiratory volume in the first second (FEV1) <0,8L or <50% of predicted value, Body mass index > 35 \* Hypoxemia, PaO2 < 60 mmHg on room air / while receiving 2L per minute on nasal oxygen

## **Study design**

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

## Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	08-04-2019
Enrollment:	66
Туре:	Actual

## **Ethics review**

Approved WMO	
Date:	31-01-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2019
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

No registrations found.

## In other registers

Register

ССМО

ID NL66993.018.18