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

No registrations found.

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

Summary

ID

NL-OMON26744

Source
Nationaal Trial Register

Brief title
The COLD study

Health condition

Interstitial lung disease

Sponsors and support

Primary sponsor: Amsterdam University Medical Center
Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

Need for (prolonged) chest tube drainage

Secondary outcome

Complications, comprehensive complication index, length of hospital stay, days with chest tube, pain, quality of life, diagnostic yield, patient preference and health care costs.

Study description

Background summary

1) RCT to compare patient- and healthcare burden of bronchoscopic cryobiopsy (followed by surgical lung biopsy in case of non-diagnostic results) versus immediate surgical biopsy in patients with an interstitial lung disease.
(performed in a population of patients fit to undergo surgical lung biopsy, n=46)
2) Observational cohort of bronchoscopic cryobiopsy in ILD
(performed in a population of patients not fit for surgical lung biopsy, n=20)

Study objective

A diagnostic strategy starting with bronchoscopic cryobiopsy is associated with a reduced need for chest tube drainage in comparison to a diagnostic strategy with immediate surgical lung biopsy, and is therefore associated with a lower patient- and healthcare burden, while remaining a similar high diagnostic yield.

Study design

3 months follow up

Intervention

Step up diagnostic strategy starting with cryobiopsy (only followed by surgical biopsy in the case of non-diagnostic cryobiopsy) vs standard (immediate surgical biopsy)

Contacts

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Eligibility criteria

Inclusion criteria

Adults with an interstitial lung disease and an indication for lung tissue sampling

Exclusion criteria

Use of clopidogrel, or other new anti-platelet therapy, or anticoagulant drugs that cannot be stopped temporarily, thrombocytopenia (< 70 x10^9/L), 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, Pregnancy

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):	01-03-2019
Enrollment:	66
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	29-03-2019
Application type:	First submission

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
NTR-new	NL7634
Other	METC Amsterdam UMC : METC2018_224

Study results