

# Comparison of forceps biopsy and cryobiopsy in bronchoscopically visible pulmonary lesions

<b>Submission date</b> 01/12/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/12/2020	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Randomised prospective controlled study for the comparison of forceps biopsy and cryobiopsy in bronchoscopically visible pulmonary lesions

**Study objectives**

In patients with endobronchially tumour suspicious lesions cryobiopsy shows a higher sensitivity than forceps biopsy.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The corresponding ethics committees and the institutional review boards approved the study protocol. All other centres will seek ethics approval before recruiting participants.

**Study design**

Prospective randomised controlled partially blinded multicentre parallel-group study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Bronchoscopically visible pulmonary lesions

**Interventions**

This was a prospective, randomised, partially blinded multicentre study. A total of 600 patients with suspected endobronchial tumours were investigated. Patients were randomised either to sampling using forceps or the cryoprobe. After obtaining biopsy samples a blinded histological evaluation was performed. Follow-up occurred until the timepoint a definitive diagnosis was obtained either by the investigated biopsy methods or by an additional diagnostic method. According to the definitive clinical diagnosis sensitivity for malignancy was evaluated. Procedure related factors such as duration of procedure (i.e. biopsy sampling plus haemostatic measures), anaesthetic requirements and also the adverse event rate were recorded. A follow-up to guarantee patients safety was not necessary in this case since the intervention was biopsy sampling for diagnostics purposes.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Sensitivity of forceps biopsy versus cryobiopsy: The biopsy technique utilised was regarded as successful, when histological confirmation of the diagnosis was achieved at the initial bronchoscopy and matched the final diagnosis. If additional tests, e.g. further bronchoscopies, surgery etc. were needed to establish the tumour diagnosis, the biopsy was regarded as not diagnostic.

**Key secondary outcome(s)**

1. Bleeding frequency and severity: none/mild (no intervention)/severe (at least one intervention for bleeding control applied)
2. The number of samples taken (per protocol the number of biopsies needed was left to the bronchoscopist's discretion with a suggested maximum limit of four samples)
3. Localisation
4. Classification of tumour into exophytic or submucosal growth
5. Level of difficulty to position the probe (easy, moderate or difficult)
6. Duration of the procedure
7. Historical parameters such as quality and size of the samples
8. Need of additional measures, e.g., immunohistology
9. Bronchoscopy technique (rigid/flexible)
10. Quality of histology
11. Influence of forceps size upon diagnostic yield and sample size
12. Diagnostic yield of forceps biopsy versus cryobiopsy in the whole study population

All assessed intra-/peri-procedural.

**Completion date**

30/10/2008

## Eligibility

**Key inclusion criteria**

1. Clinical indication for a biopsy of an endoscopically visible endobronchial lesion suspicious for tumour
2. Aged older than 18 years, either sex
3. Signed declaration of consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

593

**Key exclusion criteria**

1. Haemorrhagic diathesis/anticoagulation
2. Oxygen saturation under 2 l/min less than 90%
3. Severe underlying cardiac disease (unstable angina pectoris, myocardial infarction in the past month, decompensated cardiac insufficiency)

**Date of first enrolment**

01/06/2005

**Date of final enrolment**

30/10/2008

## Locations

**Countries of recruitment**

Germany

**Study participating centre****Department of Internal Medicine II**

Tuebingen

Germany

72076

## Sponsor information

**Organisation**

University Clinical Center Tuebingen (Germany) - represented by its management

**ROR**

<https://ror.org/00pjgXH97>

## Funder(s)

**Funder type**

Industry

**Funder Name**

ERBE Elektromedizin GmbH (Germany) - provided cryoprobes and 15 per patient for documentation and additional histological slides

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/03/2012	29/12/2020	Yes	No