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Comparison of forceps biopsy and cryobiopsy in bronchoscopically visible pulmonary lesions

Submission date	Recruitment status	[_] Prospectively registered
01/12/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/01/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/12/2020	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/06/2005

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

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

Sponsor details
c/o Dr Juergen Hetzel
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Sponsor type
University/education

Website
http://www.uni-tuebingen.de/uni/qvr/e-30/m30-01.html

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Results article	results	01/03/2012	29/12/2020	Yes	No