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Bronchoscopic Intratumoral injection of Tranexamic Acid for prevention of excessive bleeding during multiple forceps biopsy procedure

Submission date
26/10/2013

Recruitment status
No longer recruiting

Registration date
08/11/2013

Overall study status
Completed

Last Edited
12/01/2015

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Significant bleeding may occur following endobronchial forceps biopsy (a medical procedure that involves taking a small sample of tissue so that it can be examined under a microscope) or brushing
of tumors in the airways. In some cases, methods such as endobronchial instillation of iced saline lavage (washing of the organ with saline) and epinephrine may fail to control the bleeding. The present study aimed to evaluate the effectiveness and safety of a new bronchoscopic technique using intratumoral injection of tranexamic acid (IIT) for controlling bleeding during forceps biopsy in
patients with endobronchial tumors with a high risk of bleeding.

Who can participate?
Adult male and female patients suspected of lung cancer by signs, symptoms and other diagnostic
tests are eligible to enter the study.

What does the study involve?
Bronchoscopic IIT was performed in those patients who had endoscopically visible tumoral lesions
with continued endobronchial active bleeding following the first attempt of bronchoscopic sampling
by endobronchial forceps biopsy (EBB) or endobronchial needle aspiration (EBNA). Tranexamic acid
(TEA) is injected through a needle into the lesion. After 2-3 minutes of waiting, multiple forceps biopsy specimens are obtained from the lesion.

What are the possible benefits and risks of participating?
Following IIT, multiple forceps biopsies can be performed without significant bleeding. This

makes
procedure more comfortable and safe for patients and saves time for bronchoscopists.
TEA reduces blood loss during operations in a variety of clinical settings, including cardiac surgery,
major orthopedic surgery and gynecological conditions, and decreases death rates in trauma patients with significant bleeding. Adverse events associated with TEA are uncommon; nausea, diarrhea and occasionally low blood pressure have been reported with oral or rapid intravenous administration, respectively.

Where is the study run from?
The Department of Pulmonary Medicine, Meram Medical Faculty, N.E. University, Konya, Turkey.

When is the study starting and how long is it expected to run for?
The study started in October 2009 and is expected to be completed in three years.

Who is funding the study?
Meram Medical Faculty, N.E. University, Konya (Turkey).

Who is the main contact?
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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
Bronchoscopic intratumoral injection of tranexamic acid for prevention of excessive bleeding during
multiple forceps biopsy procedure in patients with endobronchial tumors with a high risk of bleeding

Acronym
BITA

Study objectives
It is hypothesised that a bronchoscopic technique using intratumoral injection of tranexamic acid (IIT)
controls bleeding during the multiple forceps biopsy procedure in patients with endobronchial tumors
with a high risk of bleeding.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Meram Medical Faculty Ethical Committee, 26/06/2009, Approval number 2009/327

Study design
Single-centre off-label use non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Lung cancer

Interventions

Transamine ampoule (tranexamic acid) is injected through a 22-gauge Wang cytology needle into the lesion in fractional amounts at various points in nominal doses from 250 to 500 mg. All patients
are followed up for a week after bronchoscopic procedures.

Rarely some lung cancer patients with drug-eluting coronary stents are on continuous dual antiplatelet therapy (aspirin and clopidogrel), and upon consultation and recommendation from the
cardiology department, these drugs are not discontinued perioperatively. Therefore,only in this category of patients, due to the high risk of bleeding, the first bronchoscopic sampling is performed
by EBNA, and after intratumoral injection of tranexamic acid, multiple EBB specimens are obtained
from the lesion.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Tranexamic acid

Primary outcome measure
Performance of multiple forceps biopsy procedure in patients with endobronchial tumors without
producing active bleeding

Secondary outcome measures
1. Adverse effects during and after IIT
2. Cost-effectiveness of the IIT

Overall study start date
13/10/2009

Completion date
18/07/2012

Eligibility

Key inclusion criteria
1. Written informed consent
2. Adults aged over 18 years, either sex
3. Patients suspected of lung cancer by signs, symptoms, chest radiograph and computed tomography and/or fluorodeoxyglucose positron emission tomography findings

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Unfit to undergo a bronchoscopy
2. History or risk of thrombosis, active thromboembolic disease, subarachnoid hemorrhage
3. A known or suspected bleeding disorder
4. Thrombocytopenia
5. Uremia
6. Disturbances of color vision

Date of first enrolment
13/10/2009

Date of final enrolment
18/07/2012

Locations

Countries of recruitment
Türkiye

Study participating centre
Department of Pulmonary Medicine
Konya
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Sponsor information

Organisation
Necmettin Erbakan (NE) University (Turkey)

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Sponsor type
University/education

ROR
https://ror.org/013s3zh21

Funder(s)

Funder type
University/education

Funder Name
Meram Medical Faculty, N.E. University, Konya (Turkey)

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	01/03/2014		Yes	No