

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/01/2015	Condition category Cancer	<input type="checkbox"/> 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?

Dr Adil Zamani

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

Türkiye

42080

Sponsor information

Organisation

Necmettin Erbakan (NE) University (Turkey)

ROR

<https://ror.org/013s3zh21>

Funder(s)

Funder type

University/education

Funder Name

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

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?
Results article	results	01/03/2014		Yes	No