

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of presence of detrusor muscle in pathology report between monopolar conventional TURBT and en-bloc TURBT in bladder mass less than 3cm without past history of bladder mass in Hashemonejad hospital from 1396 to 1397

#### Protocol summary

##### Study aim

1- Comparison of detrusor muscle in conventional TURBT and en-bloc TURBT methods 2- Comparison of surgical time in conventional TURBT and en-bloc TURBT methods 3. Comparison of bladder rupture rates in conventional TURBT and en-bloc TURBT methods 4- Comparison of bladder tumor grade in conventional TURBT and en-bloc TURBT methods 5- Comparison of mean hemoglobin reduction in conventional TURBT and en-bloc TURBT methods

##### Design

A randomized, triple-blind, parallel groups clinical trial

##### Settings and conduct

Patients underwent conventional TURBT and en bloc TURB at Hasheminejad Hospital following general or spinal anesthesia. The patient, pathologist, and analyzer were unaware of the surgical procedure (triple blindness).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Patients with single mass and peduncle mass, tumor size less than 3 cm and no previous history of bladder mass. Exclusion criteria Presence of more than one tumor, having previous history of bladder mass, tumor size greater than 3 cm

##### Intervention groups

Surgery was done in two conventional TURBT techniques using monopolar loop and distilled water for surgical treatment and en-bloc TURBT technique using monoplastic hook and distilled water for surgical treatment

##### Main outcome variables

Presence of detrusor muscle, duration of surgery, rupture of bladder, hemoglobin loss

#### General information

##### Reason for update

##### Acronym

en bloc TURB

##### IRCT registration information

IRCT registration number: **IRCT20190528043745N1**  
Registration date: **2019-11-16, 1398/08/25**  
Registration timing: **retrospective**

Last update: **2019-11-16, 1398/08/25**

Update count: **0**

##### Registration date

2019-11-16, 1398/08/25

##### Registrant information

##### Name

Koosha Kamali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4601 3954

##### Email address

kamali.k@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2018-08-23, 1397/06/01

##### Actual recruitment start date

2017-08-23, 1396/06/01

##### Actual recruitment end date

2018-08-23, 1397/06/01

**Trial completion date**

2018-08-23, 1397/06/01

**Scientific title**

Comparison of presence of detrusor muscle in pathology report between monopolar conventional TURBT and en-bloc TURBT in bladder mass less than 3cm without past history of bladder mass in Hashemonejad hospital from 1396 to 1397

**Public title**

Comparison of presence of detrusor muscle in pathology report between monopolar conventional TURBT and en-bloc TURBT

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

mass less than 3cm

**Exclusion criteria:**

past history of bladder mass

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Balance Blocked Randomization using statistical software

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

patient did not know about surgical technique.

Pathologist did not know about surgical technique.

Studied groups were introduced to analyzer as A and B groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

no matter

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

Hemmat highway

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Approval date**

2017-10-08, 1396/07/16

**Ethics committee reference number**

IR.IUMS.FMD.REC1396.9411254002

**Health conditions studied****1****Description of health condition studied**

Bladder mass

**ICD-10 code**

C67

**ICD-10 code description**

Malignant neoplasm of bladder

**Primary outcomes****1****Description**

The presence or absence of muscle tissue

**Timepoint**

Pathological report up to two weeks after surgery

**Method of measurement**

Use of a microscope by a pathologist

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: This group is related to en bloc TURB surgery and includes 30 patients. In this procedure, patients underwent either general or spinal anesthesia under en bloc TURBT surgery using monopolar hooks and distilled water for intraoperative irrigation. Their pathological specimens are examined for the presence of detrusor muscle. After tumor resection, the tumor margin is coagulated about 0.5 cm away. Then, after fixing the three-way foley catheter, the bladder is washed with normal saline. Duration of surgery as well as postoperative complications including hemoglobin loss and bladder rupture were also studied. For all patients,

40 mg mitomycin is injected into the bladder for the first six hours after surgery.

**Category**

Treatment - Surgery

**2****Description**

control group: This group is related to conventional TURB surgery and includes 30 patients. In this procedure, patients underwent either general or spinal anesthesia under conventional TURBT surgery using monopolar loop and distilled water for intraoperative irrigation. Their pathological specimens are examined for the presence of detrusor muscle. After tumor resection, the tumor margin is coagulated about 0.5 cm away. Then, after fixing the three-way foley catheter, the bladder is washed with normal saline. Duration of surgery as well as postoperative complications including hemoglobin loss and bladder rupture were also studied. For all patients, 40 mg mitomycin is injected into the bladder for the first six hours after surgery.

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hesheminejad hospital

**Full name of responsible person**

Koosha Kamali

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Vanak square

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1969714713

**Phone**

+98 21 8864 4457

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ehsanzolfi1@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Pejman Shadpour

**Street address**

Vanak square, Hasheminejad hospital

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info@hkc.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Hasheminejad hospital

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Ehsan Zolfi

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Koosha Kamali

**Position**

Associate professor

**Latest degree**

Specialist  
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## Person responsible for updating data

**Contact**  
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Iran University of Medical Sciences  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data can be published.

### When the data will become available and for how long

After the paper publication

### To whom data/document is available

All persons

### Under which criteria data/document could be used

under any circumstances

### From where data/document is obtainable

Ehsanzolfi1@gmail.com

### What processes are involved for a request to access data/document

one weel

### Comments