Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
۱۴۴۹۶۱۴۵۳۵

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

Street address

Vanak square

City

Tehran

Province

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Postal code

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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Postal code

1969714713

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Email

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

Street address

No 21, Namazi avenue, south Jannat abad,

City

Tehran

Province

Tehran

Postal code

1474746767

Phone

O098 21 46013954

Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Koosha Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ehsan Zolfi

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Urology

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Email

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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