

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of tattoo markers on marking the bladder tumor place for reTURBT :An Interventional Randomized Clinical Trial

#### Protocol summary

##### Study aim

The effect of tattoo markers in marking the tumor location in the ease of finding the tumor in patients who are candidates for Re TURBT

##### Design

A clinical trial with two groups of patients: parallel, therapeutic, balanced block randomization, single-blind (patient). Twenty patients referred to Sinai Hospital.

##### Settings and conduct

In the group of this clinical trial at Sina Hospital in Tehran, Urology Research Centre, single-blind (patient) Weber balanced block randomization will be performed on 20 patients. Patients are divided into two groups: The first group is Re-TURBT candidate patients who have markings with tattoo ink. The second group is Re-TURBT candidate patients who do not have markings with tattoo ink.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Bladder tumor patients referred for the first time (primary). The size of the tumor is less than 3 cm. The tumor is solitary. Non metastatic tumor. High grade tumor. Informed consent from patients. Exclusion criteria: Multifocal tumor. The volume of the patient's bladder should be small. The tumor is recurrent. The patient is not a candidate for reTURBT

##### Intervention groups

The present study is a single-blind randomized clinical trial study. The participant will not know the randomization method. Intervention group (Re TURBT candidate patients who have markings with tattoo ink). Control group (Re TURBT candidate patients who do not have markings with tattoo ink).

##### Main outcome variables

Determining the success rate and feasibility of identifying the location of the tumor using tattoo ink

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190624043991N24**  
Registration date: **2023-12-09, 1402/09/18**  
Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**

Update count: **0**

##### Registration date

2023-12-09, 1402/09/18

##### Registrant information

##### Name

Seyed Mohammad Kazem Aghamir

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8560

##### Email address

mkaghamir@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-20, 1402/12/01

##### Expected recruitment end date

2025-02-19, 1403/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of tattoo markers on marking the bladder tumor place for reTURBT :An Interventional Randomized Clinical Trial

**Public title**

The effect of tattoo markers in marking the Bladder tumor site

**Purpose**

Treatment

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

Bladder tumor patients who were referred for the first time (primary). The size of the tumor is less than 3 cm  
The tumor is solitary Non metastatic tumor High grade tumor Informed consent from patients

**Exclusion criteria:**

Multifocal tumor The volume of the patient's bladder should be small The tumor is recurrent The patient is not a candidate for reTURBT

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **20**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For randomization, the balanced block randomization method is used to generate blocks with a size of 4. Intervention group A and control group B have been determined. According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the Sealdenvolp online site, the generated sequence will be available to a technician outside the research team. blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected, and the type of patient group is informed to the research team through a trained technician. Based on the randomly selected envelope, the patient is placed in the group (Patients who have markings with tattoo ink) or (Patients who do not have markings with tattoo ink).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The present study is a single-blind, randomized clinical trial study. The participant will not know that he will be in the intervention group (Re TURBT candidate patients with tattoo ink) or the control group (Re TURBT candidate patients who do not have markings with tattoo ink). India ink or tattoo (an inert, colloidal suspension of carbon particles that has been used safely during colonoscopies for decades to mark the location of relevant lesions).

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Research Ethics Committee, Sina Hospital

**Street address**

Room 206, Ethics Committee Office, Second Floor, Administrative Building, Sina Hospital, Imam Khomeini Street, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Approval date**

2023-07-17, 1402/04/26

**Ethics committee reference number**

IR.TUMS.SINAHOSPITAL.REC.1402.054

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

bladder tumor

**ICD-10 code**

C67

**ICD-10 code description**

Malignant neoplasm of bladder

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

Determining the success rate and feasibility of identifying the location of the tumor using of tattoo ink

**Timepoint**

Four to six weeks after TURBT

**Method of measurement**

The necessary pathological and cytological results (complete blood test, keratin, etc.)

**Secondary outcomes**

empty

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

(Re-TURBT candidate patients who have tattoo ink)

marking for safe and successful marking of lesions in Re-TURBT patients with bladder tumor for the first time. Tattooing will be done at intervals of 1 to 2 cm, approximately 1 cm from the outer edge of the lesion, with sufficient depth (deep muscle layer) under cystoscopy guidance.

**Category**

Diagnosis

**2****Description**

Control group: (Patients who are candidates for Re-TURBT who do not have markings with tattoo ink)

**Category**

Diagnosis

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

Sina Hospital

**Full name of responsible person**

Dr Mohammad Kazem Aghamir

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Urology Research Center, Sina Hospital, Imam Khomeini St., Tehran, Iran .

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http://urc.tums.ac.ir

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

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Akbar Fotouhi

**Street address**

Sixth Floor, Central University, Quds Ave., Keshavarz Boulevard, Tehran, Iran.

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

Yes

**Title of funding source**

Tehran University of Medical Sciences

**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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Akram Mirzaei

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biology

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**Person responsible for scientific inquiries****Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Kazem Aghamir

**Position**

Head of Urology Research Center

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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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**

No - There is not a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

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

Demographic information anonymously

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

One year after publication

**To whom data/document is available**

Researchers working in academia, physicians, surgeons and hospitals

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

Any analysis can be done with the consent of the main researcher

**From where data/document is obtainable**

Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir 00982166348560 mkaghamir@tums.ac.ir

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

After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Akram Mirzaei

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biology

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