Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 salitary 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 Sealdenvelop 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8500

Fax

+98 21 6634 8553

Email

mkaghamir@tums.ac.ir

Web page address

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.

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3685

Fax

+98 21 8163 3686

Email

vcr@tums.ac.ir

Web page address

http://vcr.tums.ac.ir/

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

Street address

Urology Research Center- Sina Hospital - Imam Khomeini St

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6634 8560

Fax

+98 21 6634 8561

Email

mirzaee.scholar@gmail.com

Web page address

https://URC@tums.ac.ir

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
Street address
Urology Research Center- Sina Hospital - Imam Khomeini St
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8560
Fax
+98 21 6634 8561
Email
mkaghamir@tums.ac.ir
Web page address
http://urc.tums.ac.ir

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
Street address
Urology Research Center- Sina Hospital - Imam Khomeini St
City
تهران
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8560
Fax
+98 21 6634 8561
Email
mirzaee.scholar@gmail.com
Web page address
https://URC@tums.ac.ir

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