Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparing the intravesical effect of gemcitabine with distilled water after trans urethral resection of tumor on prevention of recurrence in non-muscle-invasive bladder cancer

Protocol summary

Study aim

Comparing the intravesical effect of gemcitabine with distilled water after transurethral resection of tumor on prevention of recurrence in non-muscle-invasive bladder cancer

Design

A double-blind, randomized-controlled clinical trial study with parallel groups and phases 3 on134 patients. Patients will be divided into distilled water and gemcitabine groups using simple randomization.

Settings and conduct

In this study, 134 patients of non-muscle-invasive bladder cancer undergoing transurethral resection of tumor (TURT) in Urmia Imam Khomeini hospital will be included. The study will be conducted as a double-blind clinical trial. The patients and the researcher who will be evaluating the outcomes will be blind about the allocation of patients into distilled water or gemcitabine groups. Group names will be encoded with the letters A and B.

Participants/Inclusion and exclusion criteria

In this study, 134 patients of non-muscle-invasive bladder cancer undergoing transurethral resection of tumor (TURT) will be included. Inclusion criteria will be new cases of tumors with tumor size less than or equal to 3 cm and low-grade tumors on cystoscopy. patients with frequent recurrence will be excluded.

Intervention groups

In the intervention group, at the end of the surgery, 2000 mg of gemcitabine will be dissolved in 100 ccs of normal saline and injected into the duct through a catheter and the catheter will be closed for 3 hours. In the control group, at the end of the surgery, a three-way catheter will be inserted and the bladder will be washed continuously with sterile distilled water for three hours.

Main outcome variables

Tumor size and Tumor recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220207053961N1**
Registration date: **2022-04-03, 1401/01/14**
Registration timing: **prospective**

Last update: **2022-04-03, 1401/01/14**
Update count: **0**

Registration date

2022-04-03, 1401/01/14

Registrant information

Name

Mohammad Sadri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 7286

Email address

sadri.m@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the intravesical effect of gemcitabine with distilled water after trans urethral resection of tumor on prevention of recurrence in non-muscle-invasive bladder cancer

Public title
The effect of intravesical gemcitabine on prevention of recurrence in non-muscle-invasive bladder cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with non-muscle-invasive bladder cancer Patients candidate of trans urethral resection of tumor (TURT) Tumor size less than or equal to 3 cm Low grade tumor on cystoscopy Diagnosed tumors in first time
Exclusion criteria:
Frequent recurrence Tumor size above 3 cm
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **134**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into distilled water and gemcitabine groups using simple randomization. So that, based on determining sample in each group, the letters A (distilled water) and B (gemcitabine) will be written on the cards and all the cards will be placed in an envelope. then patients will be assigned to A or B groups by picking up cards.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be conducted as a double-blind clinical trial. The patient and the researcher who will be evaluating the outcomes will be blind about the allocation of patients into distilled water or gemcitabine groups. Group names will be encoded with the A and B letters.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2021-11-10, 1400/08/19
Ethics committee reference number
IR.UMSU.REC.1400.341

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
Tumor size
Timepoint
Three and six months after surgery
Method of measurement
In millimeters on sonography

2

Description
Tumor recurrence
Timepoint
Three and six months after surgery
Method of measurement
Having a recurrence based on sonography

Secondary outcomes

1

Description
Tumor site
Timepoint
Three and six months after surgery

Method of measurement
Sonography

Intervention groups

1

Description
Intervention group: At the end of the surgery, 2000 mg of gemcitabine will be dissolved in 100 ccs of normal saline and injected into the duct through a catheter and the catheter will be closed for 3 hours.
Category
Treatment - Other

2

Description
Control group: At the end of the surgery, a three-way catheter will be inserted and the bladder will be washed continuously with sterile distilled water for three hours.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Dr. Mohammad Sadri
Street address
Imam Khomeini hospital, Ershad street, Modarres Blvd., Urmia, Iran.
City
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sadri.m@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
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5714783734
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gholizadeh.s@umsu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Mohammad Sadri
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Urology
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Imam Khomeini hospital, Ershad street, Modarres Blvd., Urmia, Iran.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Mohammad Sadri
Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of patient information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The data will not be published individually and the results will be available as published article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers

Under which criteria data/document could be used

Not applicable

From where data/document is obtainable

Email address of corresponding author

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

Email address: sadri.m@umsu.ac.ir

Comments