

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 on 134 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 (TUR) 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 (TUR) 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 (TUR) 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, Jihad 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.

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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

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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

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

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Full name of responsible person

Dr. Mohammad Sadri

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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