

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Assessment of the therapeutic effect of intravesical Gemcitabine compared with intravesical BCG in non-muscle invasive urothelial carcinoma of the bladder, subgroups of intermediate-risk

Protocol summary

Study aim

Prevent recurrence of bladder cancer in patients with non-muscle invasive bladder cancer subgroup of intermediate-risk by using intravesical Gemcitabine.

Design

Randomized clinical trial with a control group, two parallel-group, not blind on 110 patients

Settings and conduct

The study will perform on patients with bladder masses who referred to Shohada-e Tajrish Hospital who had no history of TURT surgery. Immediately after TURT, intravesical injection of Gemcitabine is performed for all patients. Patients whose pathology is non-muscle invasive and are in the intermediate-risk subgroup are included in the study. Patients will be randomly divided into two groups by computer. The sample size of each group will be 55 according to statistical calculations. This trial will have a control group and will not be blind. The first group undergoes 6 intravesical injections of Gemcitabine at intervals of one week. The second group undergoes 6 intravesical BCG injections at intervals of one week. Then, according to the guideline protocol, patients undergo cystoscopy at regular intervals and are examined for tumor recurrence.

Participants/Inclusion and exclusion criteria

Patients with non-muscle invasive bladder cancer, the subgroup of intermediate-risk will enter the study. Patients should not have the history of using intravesical injections. Patients should not have a history of previous TURT. Pregnant women and patients with immunodeficiency conditions and also patients who have ruptured during TURT, will exclude.

Intervention groups

Intravesical injection of Gemcitabine 6 times with one-week intervals in the intervention group and injection of intravesical BCG 6 times with one-week intervals in the control group

Main outcome variables

Tumor recurrence is the main consequence of the study, which will evaluate by cystoscopy in predetermined follow-up.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200402046915N1**

Registration date: **2020-10-04, 1399/07/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-04, 1399/07/13**

Update count: **0**

Registration date

2020-10-04, 1399/07/13

Registrant information

Name

Seyyed Ali Hojjati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2282 9356

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sah.hojjati@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Assessment of the therapeutic effect of intravesical Gemcitabine compared with intravesical BCG in non-muscle invasive urothelial carcinoma of the bladder, subgroups of intermediate-risk

Public title

Assessment of the therapeutic effect of intravesical Gemcitabine in patients with bladder cancer.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All the patients with bladder cancer who are not candidates for chemotherapy or bladder removal surgery. Patients with no history of TURT surgery. Patients have no history of intravesical injections. Patients respond to the initial pathology under the moderate risk group with no muscle involvement.

Exclusion criteria:

Patients with ruptured bladder during TURT surgery. Patients with immunodeficiency. Patients who are pregnant. Patients who are unable to perform TURT due to urethral stricture or urethral obstruction. Patients with a history of intravesical injections.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 110

Randomization (investigator's opinion)

Randomized

Randomization description

The 110 patients who underwent TURT were received intravesical Gemcitabine for two hours immediately after TURT surgery. Then patients were randomly divided into two groups A and B by a computer-aided program. Group A patients were treated with intravesical Gemcitabine (according to the protocol program) and Group B patients were treated with intravesical BCG. (according to the protocol program)

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shohada Tajrish Clinical Research Development Unit

Street address

Shohada Tajrish Hospital , Shahr-dari Street , Tajrish Square

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2020-07-28, 1399/05/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.507

Health conditions studied

1

Description of health condition studied

Bladder Cancer

ICD-10 code

C67.9

ICD-10 code description

Malignant neoplasm of bladder, unspecified

Primary outcomes

1

Description

Recurrence of bladder cancer

Timepoint

First, a cystoscopy will be performed one month after the last injection into the bladder. Then, in the first year, it will be evaluated by cystoscopy every 3 months, and then every 6 months by cystoscopy.

Method of measurement

Direct observation inside the bladder through cystoscopy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with non-muscle invasive bladder cancer subgroup of intermediate-risk who undergo 6 intravesical injections of 1 g of vial

Gemcitabine for 2 hours at one-week intervals.

Category

Treatment - Drugs

2

Description

Control group: Patients with non-muscle invasive bladder cancer subgroup of intermediate-risk who undergo 6 intravesical injections of BCG for 2 hours at one-week intervals.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Tajrish hospital

Full name of responsible person

Seyyed Ali Hojjati

Street address

Shohada Tajrish Hospital , Shahr-dari Street , Tajrish Square

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sah.hojjati@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti Medical University , Near the Taleghani Hospital , Yaman Street , Shahid Chamran Highway

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1985717443

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info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Ali Hojjati

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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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

No - There is not 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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome can be shared.

When the data will become available and for how long

Start of access period 6 months after publishing the results.

To whom data/document is available

Our data will only be available to researchers working in the academic centers.

Under which criteria data/document could be used

Possible analyzes are performed in SPSS software.

From where data/document is obtainable

Applicants should email the following e-mail address to receive the documents: sah.hojjati@sbmu.ac.ir

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

The applicant can submit his / her request and receive the documents 6 months after the publication of the results via the following e-mail: sah.hojjati@sbmu.ac.ir

Comments