

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the efficacy of oxybutynin and phenazopyridine and celecoxib with placebo in the treatment of urinary tract symptoms after BCG therapy in bladder tumors patients

Protocol summary

Study aim

The efficacy of oxybutynin and phenazopyridine and celecoxib and placebo in controlling BCG-induced urinary and systemic symptoms and obtaining the correct protocol for BCG administration is.

Design

In this study, 120 patients with bladder tumor and candidate for treatment of intercostal BCG who were admitted to the Hasheminejad Hospital in Tehran were selected. The participants were randomly divided into four groups of 30, randomly assigned to each group. The patients underwent the treatment at the same time during the six weeks of BCG treatment, and weekly signs were recorded in the designed questionnaire and were prepared for statistical analysis.

Settings and conduct

This study is a randomized clinical trial that will be done by parallel groups in four groups. The study population was adult bladder tumor candidate for treatment of Bacillus Calmette-Guérin (BCG) as a 6-week induction protocol that was administered to the Hashemi Nejad Clinic during the year 1395.

Participants/Inclusion and exclusion criteria

Inclusion Criteria of the study are bladder tumor that candidate for Bacillus Calmette-Guérin (BCG) Therapy and aged over 18 years. Exclusion criteria include history of pelvic surgery, severe urinary tract symptoms, overactive bladder, complete urinary incontinence, traumatic catheterization, active TB symptoms.

Intervention groups

In accordance with the pharmaceutical company, all treatments in the same coating were prepared in a capsule form that were not indistinguishable, and one of the groups was treated with oxybutynin 10 mg daily and the next group of phenazopyridine three times daily and the next group of celecoxib 100 mg and the last group received placebo. Within 6 weeks will be tracked.

Main outcome variables

dysuria, frequency, urgency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171225038070N1**

Registration date: **2018-07-08, 1397/04/17**

Registration timing: **retrospective**

Last update: **2018-07-08, 1397/04/17**

Update count: **0**

Registration date

2018-07-08, 1397/04/17

Registrant information

Name

Javad Nikbakht

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8864 4435

Email address

nikbakht.j@kar.iuums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-07-05, 1395/04/15

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

2016-07-05, 1395/04/15

Actual recruitment end date

2017-12-21, 1396/09/30 Trial completion date empty	
Scientific title Comparison of the efficacy of oxybutynin and phenazopyridine and celecoxib with placebo in the treatment of urinary tract symptoms after BCG therapy in bladder tumors patients	Patients were selected according to a randomized table, and the presenter and the investigator were not included in the selected medication. In the case of a person in the study, the medication was placed in the same coat of coat. The designer was blinded to the use of a randomized table and sealed envelopes in which the names of the drugs were used. In the case of the researcher, according to the coding of the participating groups and the naming of groups with blind numbers.
Public title Assessing the effectiveness of oxybutynin and phenazopyridine and celecoxib in reducing complications in the treatment of bladder tumors.	Placebo Used Assignment Parallel Other design features
Purpose Treatment Inclusion/Exclusion criteria Inclusion criteria: bladder cancer candidates for BCG therapy Non muscle bladder cancer Exclusion criteria: history of pelvic surgery severe urinary tract symptoms (IPSS over 20) overactive bladder complete urinary incontinence traumatic catheterization active TB symptoms	Secondary Ids empty Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Iran University of Medical Sciences Street address Iran University of Medical Sciences, Hemmat Highway City Tehran Province Tehran Postal code 1969714713 Approval date 2016-12-10, 1395/09/20 Ethics committee reference number IR.IUMS.REC 1395.9311254004
Age From 18 years old Gender Both	
Phase 3	
Groups that have been masked • Participant • Care provider • Investigator • Outcome assessor • Data analyser	
Sample size Target sample size: 120 Actual sample size reached: 120	
Randomization (investigator's opinion) Randomized	
Randomization description Patients were divided into four group with random allocation process. The randomized blocks were randomly assigned to the researcher by the design consultant in sealed envelopes. . The creation of a randomized table with the STATA software and its output will be random letters A, B, C, D for treatment groups 1 to 4. After qualifying for inclusion in the study and lack of exclusion criteria by one of the researchers, the envelope designation for the candidate number of the candidate for treatment of BCG is opened and the type of treatment A, B, C, D specified and the person will be treated once a week. And the drug will be delivered to the patient. In co-ordination with the pharmaceutical company, all treatments in the same coatings are provided in capsule form that can not be differentiated	Health conditions studied <u>1</u> Description of health condition studied Malignant neoplasm of bladder ICD-10 code C67 ICD-10 code description Malignant neoplasm of bladder
Blinding (investigator's opinion) Double blinded Blinding description	Primary outcomes <u>1</u> Description frequency Timepoint Six consecutive weeks at the same time as the induction treatment period for BCG.The days of 0, 7,14,21,28,35 of the intervention Method of measurement

Ask the patient and register in the questionnaire

Secondary outcomes

1

Description

urgency

Timepoint

Six consecutive weeks at the same time as the induction treatment period for BCG. The days of 0, 7, 14, 21, 28, 35 of the intervention

Method of measurement

Ask the patient and register in the questionnaire

2

Description

Urine painful

Timepoint

Six consecutive weeks at the same time as the induction treatment period for BCG. The days of 0, 7, 14, 21, 28, 35 of the intervention

Method of measurement

Ask the patient and register in the questionnaire

3

Description

Fever

Timepoint

Six consecutive weeks at the same time as the induction treatment period for BCG. The days of 0, 7, 14, 21, 28, 35 of the intervention

Method of measurement

Thermometer

4

Description

Constipation

Timepoint

Six consecutive weeks at the same time as the induction treatment period for BCG. The days of 0, 7, 14, 21, 28, 35 of the intervention

Method of measurement

Ask the patient and register in the questionnaire

5

Description

heart burn

Timepoint

Six consecutive weeks at the same time as the induction treatment period for BCG. The days of 0, 7, 14, 21, 28, 35 of the intervention

Method of measurement

Ask the patient and register in the questionnaire

6

Description

Feeling dry mouth

Timepoint

Six consecutive weeks at the same time as the induction treatment period for BCG. The days of 0, 7, 14, 21, 28, 35 of the intervention

Method of measurement

Ask the patient and register in the questionnaire

7

Description

Flu-like symptoms

Timepoint

Six consecutive weeks at the same time as the induction treatment period for BCG. The days of 0, 7, 14, 21, 28, 35 of the intervention

Method of measurement

Ask the patient and register in the questionnaire

8

Description

arthralgia

Timepoint

Six consecutive weeks at the same time as the induction treatment period for BCG. The days of 0, 7, 14, 21, 28, 35 of the intervention

Method of measurement

Ask the patient and register in the questionnaire

Intervention groups

1

Description

Intervention group1: Receive oxybutinine 5 mg every 12 hours for six weeks BCG treatment

Category

Treatment - Drugs

2

Description

Intervention group2: phenazopyridine 100 mg every 8 hours for six weeks BCG treatment

Category

Treatment - Drugs

3

Description

Intervention group3: Receive celecoxib 100 mg every 12 hours for six weeks BCG treatment

Category

Treatment - Drugs

4

Description

Control group: Receive placebo (Starch-filled capsules) every 12 hours for six weeks of BCG treatment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashemi Nejad Hospital

Full name of responsible person

Javad Nikbakht

Street address

Vali Nejad Ave., Vali Asr St., Vanac Sq.

City

Tehran

Province

Tehran

Postal code

1969714713

Phone

+98 21 8670 5503

Email

javad.nikbakht64@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mehrdad Eftekhari

Street address

Vali Nejad Ave, Vali asr Blvd, Vanac Sq

City

Tehran

Province

Tehran

Postal code

1969714713

Email

javad.nikbakht64@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Javad Nikbakht

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

Street address

Hashemi Nejad Hospital, Vali Nejad Ave., Vali Asr St.

City

Tehran

Province

Tehran

Postal code

969714713

Phone

+98 21 8864 4435

Email

javad.nikbakht64@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Javad Nikbakht

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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Phone

+98 21 8864 4435

Email

javad.nikbakht64@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Javad Nikbakht

Position

resident

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Urology

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Province

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Postal code

1969714713

Phone

+98 21 8864 4435

Email

javad.nikbakht64@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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