Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 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

inclution Criteria of the study are bladder tumor that candidate for Bacillus Calmette–Guérin (BCG) Therapy and aged over 18 years. Exclution 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 phenazoperidine 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.iums.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

Public title

Assessing the effectiveness of oxybutynin and phenazopyridine and celecoxib in reducing complications in the treatment of bladder tumors.

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

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

Blinding (investigator's opinion)

Double blinded

Blinding description

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.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

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

Health conditions studied

1

Description of health condition studied

Malignant neoplasm of bladder

ICD-10 code

C67

ICD-10 code description

Malignant neoplasm of bladder

Primary outcomes

1

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 treatmentIntervention group:
Category
Treatment - Drugs

3

Description
Intervention group3: Receive celecxibe 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.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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
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Other areas of specialty/work
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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