Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy and safety evaluation of modify maintenance instillation Bacillus-calmette-guerin (BCG) in , with stage Ta high grade and/or multiple and/or large and T1 bladder cancer

Protocol summary

Study aim

Evaluation of the efficacy and safety of intravesical instillation of Bacillus- calmette-guerin (BCG) by modified maintenance method in patients with bladder cancer with high grade , large or multiple Ta and T1 .

Design

In a parallel double-blind randomized trial study,64 patients with non-muscle invasive bladder cancer referred to Labbafinejad Hospital(Tehran-Iran) were randomly divided into two groups of 32 patients. All patients in the study were given an intravesical BCG instillation one month after transurethral resection of tumor.Based on the table of random numbers generated by random allocation software, In a group BCG instillation was continues for up to six months(intervention group) and the other group that received only the induced dose (control group).Patients followed every 3 months to 2 years in terms of recurrence and progression by cytology and cystoscopy.

Settings and conduct

In a parallel double-blind randomized trial study,64 patients with non-muscle invasive bladder cancer referred to Labbafinejad Hospital(Tehran-Iran) were randomly divided to two groups of 32 patients.

Participants/Inclusion and exclusion criteria

Patients with non-muscle invasive bladder cancer (Ta and T1). Have a history of transurethral resection of tumor one month before BCG therapy. Have no previous history of BCG instillation. Do not have contraindications to BCG instillation.

Intervention groups

Intervention group: Patients with non-muscle invasive bladder cancer (Ta and T1) that in addition to receiving the induction dose on a monthly basis, intravesical BCG instillation, continues for up to six months. Control group: A group of patients with non-muscle invasive bladder cancer (Ta and T1) who received only the induced dose of intravesical instillation of BCG.

Main outcome variables

Modified BCG instillation;Recurrence rate;Progress rate;Acceptance rate by patients;Complications; Gender;Age

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220302054165N1**
Registration date: **2022-07-02, 1401/04/11**
Registration timing: **retrospective**

Last update: **2022-07-02, 1401/04/11**
Update count: **0**

Registration date

2022-07-02, 1401/04/11

Registrant information

Name

Behzad Narouie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2230 6775

Email address

narouie@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2021-03-06, 1399/12/16

Actual recruitment start date
2013-05-22, 1392/03/01
Actual recruitment end date
2021-03-06, 1399/12/16
Trial completion date
2021-03-06, 1399/12/16

Scientific title
Efficacy and safety evaluation of modify maintenance instillation Bacillus- calmette-guerin (BCG) in , with stage Ta high grade and/or multiple and/or large and T1 bladder cancer

Public title
Efficacy and safety of modify maintenance instillation Bacillus- calmette-guerin (BCG) in bladder cancer
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with non-muscle invasive bladder cancer (stage Ta and T1). Have a history of transurethral resection of tumor (TURT) one month before Bacillus-calmette-guerin (BCG) therapy. Have no previous history of BCG instillation. Do not have contraindications to BCG instillation.
Exclusion criteria:
Patients with muscle invasive bladder cancer Have a history of transurethral resection of tumor (TURT) more than one month before Bacillus-calmette-guerin (BCG) therapy. Have previous history of BCG instillation. Have contraindications to BCG instillation.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**
Actual sample size reached: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
This prospective randomized clinical trial study, according to the sample size obtained, 64 patients with non-muscle invasive bladder cancer referred to Labbafinejad Hospital (Tehran-Iran)who met the inclusion criteria were randomly divided into two groups of 32 patients. All patients in the study were given an intravesical BCG instillation one month after transurethral resection of tumor. Based on the table of random numbers generated by random allocation software in regard to simple random allocation with principle analyzer assigned patients to a randomly administered BCG instillation was given to a group of randomly selected patients for up to six months (intervention group) and the other group that received only the induced dose (control group). STATA software and RALLOC command are used to assign two groups of random numbers to two treatment groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient does not know which group he or she belongs to, and the researcher , outcome assessor and the data analyst do not know which group they are evaluating. Participants, researchers, and outcome assessors are unaware of the allocation of study groups. Concealment and splitting into random groups is done by the clinical caregiver.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urology and Nephrology Research Center, Shahid Beheshty University of Medical Sc
Street address
No.44(103), Boostan 9 Alley , Pasdaran Street ,Tehran
City
Tehran
Province
Tehran
Postal code
1666668111
Approval date
2013-03-12, 1391/12/22
Ethics committee reference number
IR.SBMU.UNRC.9112.2

Health conditions studied

1

Description of health condition studied
Bladder Cancer
ICD-10 code
C67
ICD-10 code description
Malignant neoplasm of bladder

Primary outcomes

1

Description
Acceptance rate by patients
Timepoint
After induction dose and then every month for up to 6 months
Method of measurement
Visit and follow up the patients

2

Description
Complications
Timepoint
After induction dose and then every month for up to 6 months
Method of measurement
Patient symptoms and complaints

Secondary outcomes

1

Description
Recurrence rate
Timepoint
Every 3 months to 2 years
Method of measurement
laboratory tests , cytology and cystoscopy

2

Description
Progress rate
Timepoint
Every 3 months to 2 years
Method of measurement
laboratory tests , cytology and cystoscopy

Intervention groups

1

Description
Intervention group: A group of randomly selected patients received an intravesical injection of Bacillus-Calmette-Guerin (BCG) every week for up to 6 weeks and then a monthly intravesical injection of BCG Continues until it lasts six months. A vial of BCG made in Iran and Pasteur Pharmaceutical Company is suspended in 50 cc of saline without preservative and inserted into the bladder with a catheter and stays in place for up to two hours.
Category
Prevention

2

Description
Control group: A group of randomly selected patients receive an induced dose of bacillus-Calmette-Guerin (BCG) intravesical every week for up to 6 weeks. A vial of BCG made in Iran and Pasteur Pharmaceutical Company is suspended in 50 cc of saline without preservative and inserted to the bladder with a catheter and stays in position for up to two hours.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinejad Hospital
Full name of responsible person
Dr Nasser Shakhssalim
Street address
No.44(103), Boostan 9 Alley , Pasdaran Street
City
Tehran
Province
Tehran
Postal code
1666668111
Phone
+98 21 2277 0954
Email
shakhssalim@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
No.44(103), Boostan 9 Alley , Pasdaran Street ,Tehran
City
Tehran
Province
Tehran
Postal code
1666668111
Phone
+98 21 2277 0954
Email
basiri@unrc.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Urology and Nephrology Research Center
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

Nasser Shakhssalim

Position

Professor of Urology

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

No.44(103), Boostan 9 Alley , Pasdaran Street

City

Tehran

Province

Tehran

Postal code

1666668111

Phone

+98 21 2277 0954

Email

shakhssalim@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nasser Shakhssalim

Position

Professor of Urology

Latest degree

Specialist

Other areas of specialty/work

Urology

Street address

No.44(103), Boostan 9 Alley , Pasdaran Street

City

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Province

Tehran

Postal code

1666668111

Phone

+98 21 2277 0954

Email

shakhssalim@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nasser Shakhssalim

Position

Professor of Urology

Latest degree

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Other areas of specialty/work

Urology

Street address

No.44(103), Boostan 9 Alley , Pasdaran Street

City

Tehran

Province

Tehran

Postal code

1666668111

Phone

+98 21 2277 0954

Email

shakhssalim@sbmu.ac.ir

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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The personal data of the study participants and its main outcome will be shared after the individuals are not identified.

When the data will become available and for how long

After final report : September 2022

To whom data/document is available

- Urology and Nephrology Research Center - Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Similar research projects

From where data/document is obtainable

Urology and Nephrology Research Center

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

According to the rules of the Urology and Nephrology Research Center

Comments