

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effect of vitamin E on superficial bladder cancer recurrence

Protocol summary

Summary

This randomized controlled clinical trial will be conducted to evaluate the effect of vitamin E on bladder cancer recurrence. Patients diagnosed with a single, low-grade, superficial bladder tumor of less than 3 cm in diameter will be included in the study; Patients with accompanying carcinoma in situ (CIS) are excluded from the study. The patients will be randomly divided into two groups (randomization is simple as one among in referring order); one with oral intake of vitamin E (400 IU daily at night before sleep) and the control group with no intervention. None of the patients receive intravesical chemotherapy. The main outcome is recurrence rate and will be compared between two groups. The patients will be followed every three months with urine analysis and bladder ultrasound. Cystoscopy will be performed for microscopic hematuria or urinary symptoms during follow up. Cystoscopy will be done for all patients in the third- and the twelfth- month- follow up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105235527N2**

Registration date: **2011-05-25, 1390/03/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-25, 1390/03/04

Registrant information

Name

Hamidreza Zia

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-02-04, 1388/11/15

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin E on superficial bladder cancer recurrence

Public title

Effect of vitamin E on bladder cancer recurrence

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients diagnosed with a single, low-grade, superficial bladder tumor of less than 3 cm in diameter. Exclusion criteria: Patients with accompanying carcinoma in situ (CIS)

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description**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**

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Science, hezar jirib street

City

Isfahan

Postal code**Approval date**

2010-02-02, 1388/11/13

Ethics committee reference number

388477

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**

Bladder cancer recurrence

Timepoint

Every 3 months

Method of measurement

Cystoscopy, urine analysis and sonography

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: after transurethral resection of bladder tumor intake of vitamin E (400 IU daily at night before sleep) and follow up every 3 months

Category

Treatment - Drugs

2**Description**

Control group: after transurethral resection of bladder tumor no medication intake, cystoscopy and sonography done every 3 months

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person**Street address****City**

Isfahan

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

Vice Chancellery for Research, Isfahan University of Medical Sciences

Full name of responsible person

Mrs.Toghyani

Street address

Isfahan University of Medical Sciences, Hezar jerib street

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellery for Research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty