

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jun 2026

Clinical trial of a chosen drug of Persian medicine on dysuria during radiotherapy for localized prostate cancer

Protocol summary

Summary

The aim of this study is investigating the effect of a chosen drug of Persian medicine on dysuria during radiotherapy for localized prostate cancer. The statistical sample of the study includes 60 patients suffering from prostatic Adenocarcinoma in Shohada Tahjri Hospital of Shahid Beheshti University of Medical Sciences who are under treatment by Radiotherapy. They must be able to Express dysuria and must not have foley catheter and must sign informed written consent. patients are randomly divided into interfering group and control group; One Group of these patients receives chosen drug and the other one receives Placebo during radiotherapy (about two months). Any Drug sensitivity and positive urine culture indicative of infection are Exclude criteria. Patients are visited every two weeks and evaluated with a 5 degree scoring system adopted from International Prostate Symptom Score (I-PSS) and intensity of dysuria is measured by a scoring system between zero to ten (zero meaning no irritation and ten meaning no tolerable dysuria). At the end of two months, data will be recorded and analysed at the end of the research.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100711026N1**

Registration date: **2013-12-09, 1392/09/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-09, 1392/09/18

Registrant information

Name

Amir Mohammad Jaladat

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

drjaladat@gmail.com

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-10-27, 1392/08/05

Expected recruitment end date

2014-03-16, 1392/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of a chosen drug of Persian medicine on dysuria during radiotherapy for localized prostate cancer

Public title

Effect of a chosen drug of Persian medicine on dysuria during radiotherapy for localized prostate cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients who are planed radiotherapy with impression of prostate adenocarcinoma and signed informed consent, those who are able to Express dysuria and do not have not have foley catheter. exclusion criteria: Drug or placebo sensitivity and positive urine culture indicative of infection.

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Institute for Islamic and Complementary
Medicine (RICM)

Street address

Pyrnia Alley, Lalezarno Ave. Jomhoori Eslami St.
Tehran, Iran

City

Tehran

Postal code**Approval date**

2012-12-09, 1391/09/19

Ethics committee reference number

934/ط م/26پ

Health conditions studied**1****Description of health condition studied**

prostate cancer

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

Primary outcomes**1****Description**

Dysuria

Timepoint

Weekly during radiotherapy

Method of measurement

A modified IPSS (International Prostate Symptom Score)

Secondary outcomes**1****Description**

Dysuria severity

Timepoint

Weekly during radiotherapy

Method of measurement

Visual Analog Scale 0-10

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

All patients in intervention group take powder of Malva
sylvestris in 5mg packets twice a day orally with a glass
of water.

Category

Prevention

2**Description**

All patients in control group take powder of placebo
which is designed for this study in 5mg packets twice a
day orally with a glass of water.

Category

Placebo

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

Shohadaie Tajrish Hospital

Full name of responsible person**Street address**

Shohadaie Tajrish Hospital, Tajrish

City

Tehran

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

Tehran University of Medical Sciences

Full name of responsible person

Dariush Mahmoodi

Street address

Office of Vice Chancellor for Research, Third floor,

Faculty of Traditional Medicine, Behesht St., Vahdat
Eslami St. (South Hafiz), Tehran

City

Tehran

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

Yes

Title of funding source

Tehran 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**Name of organization / entity**

Tehran University of Medical Sciences, department-of-
traditional-medicine

Full name of responsible person

Amir Mohammad Jaladat

Position

MD

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Tehran University of Medical Sciences Faculty of
Pharmacy

Full name of responsible person

Gholamreza Amin

Position

PhD

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Person responsible for updating data

Contact**Name of organization / entity**

School of Iranian traditional medicine, Tehran
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Amir Mohammad Jaladat

Position

MD

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Behesht Clinic, Behesht St., Vahdat-e Eslami st.
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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