

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of the Effect of Chicory-Fumitory Syrup and megestrol in hot flashes in prostate cancer patients

Protocol summary

Study aim

The effect of Chicory-Fumitory syrup in comparison with megestrol in hot flashes caused by androgen deprivation therapy in prostate cancer patients referred to cancer clinic of Labafinejad hospital in 2019-20.

Design

Clinical trial, Randomized, Comparison between traditional medicine product and conventional intervention

Settings and conduct

Method: firstly, we will evaluate the number and severity of hot flashes in first week of study as baseline and then, we will evaluate the number and severity of hot flashes in 4 weeks of intervention in two groups. Place of intervention: oncology clinic of Labafinejad hospital, Tehran, Iran.

Participants/Inclusion and exclusion criteria

The inclusion criteria of this trial are listed below: 1.Age above 18 2.To have prostate cancer 3.To be under androgen deprivation therapy and complaining of hot flashes Non-entry criteria are listed below: 1.Not having patient inform consent 2.Being under or about to chemotherapy/radiotherapy and surgery 3.Starting ADT <4 weeks before trial and alteration in ADT plan within 8 weeks after trial. 4.Number of hot flashes <2 per day and <14 in a week. 5.Complaining of hot flashes < 2 weeks before trial 6.Taking anti depressant drug during 4 last weeks (e.g. SSRIs) 7.Survival less than 6 months 8.Metastatic cancer 9.To have advanced kidney and liver diseases 10.To have coagulation and vascular disorders

Intervention groups

- 1.First group: those who get Chicory-Fumitory syrup
- 2.Second group: those who get Megestrol

Main outcome variables

Number of hot flashes, Severity of hot flashes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190112042333N1**
Registration date: **2019-01-26, 1397/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-26, 1397/11/06**

Update count: **0**

Registration date

2019-01-26, 1397/11/06

Registrant information

Name

Sajjad Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 3521

Email address

drsadeghi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Chicory-Fumitory Syrup and megestrol in hot flashes in prostate cancer patients

Public title

The effect of Chicory-Fumitory Syrup and megestrol in hot flashes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 To be a prostate cancer patient To be under ADT therapy and complaining hot flashes

Exclusion criteria:

Metastatic Cancer Liver or kidney disorders Being under treatment for hot flashes

Age

From **18 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done by Randomizer software, before starting the trial. Patients who have inclusion criteria, are randomly assigned into one of the two groups: syrup or Megestrol tablet.

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

Ethical committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2019-01-06, 1397/10/16

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.826

Health conditions studied

1

Description of health condition studied

Prostate Cancer, Hot flashes

ICD-10 code

C61

ICD-10 code description

Malignant neoplasm of prostate

Primary outcomes

1

Description

The number of hot flashes: average of frequency during a week according to based on Daily Diary of Hot flashes.

Timepoint

Daily

Method of measurement

Calculation the average of frequency of hot flashes in a week

2

Description

Severity of hot flashes: average of severity during a week according to based on Daily Diary of Hot flashes.

Timepoint

Daily

Method of measurement

Calculation the average of severity scores of hot flashes in a week

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (1): Chicory and Fumitory Syrup contains hydro alcoholic extracts of Chicory and Fumitory with dosage of 7 ml/ daily divided to 2 doses.

Category

Treatment - Drugs

2

Description

Intervention group (2): Megestrol tablet, 20 milligram 2 times daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Oncology clinic of Labbafinejad hospital

Full name of responsible person

Sajjad Sadeghi

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No.8 Shams Alley, Vali-e-Asr Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

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info@sbmu.ac.ir

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sajjad Sadeghi

Position

MD, PhD Candidate

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Publishing results in form of a PhD thesis and an article indexing in ISI

When the data will become available and for how long

after PhD thesis defence

To whom data/document is available

Public

Under which criteria data/document could be used

for research reasons

From where data/document is obtainable

Shahid Beheshti University of Medical Sciences

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

approving by responsible officer

Comments