Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the effect of oral nano formulation of silymarin in non metastatic prostate cancer patients after radical prostatectomy

Protocol summary

Study aim
Evaluating the efficacy of oral nano formulation of silymarin in patient with non metastatic prostate cancer after radical prostatectomy

Design
randomized double blinded placebo controlled clinical trial

Settings and conduct
This study will performed in oncology and radiotherapy ward of Imam Reza hospital, affiliated to Mashhad University of Medical Sciences, Mashhad, Iran. Patients, clinical oncologist, pharmacy student, and clinical pharmacy will be blind in this study about medicine or placebo allocation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Intermediate_risk cancer with Gleason score<8 ; Life expectancy more than 10 years. Exclusion criteria: Patient with history of chemotherapy, radiotherapy or hormone therapy ; patients with chronic liver, kidney or heart disease ; patient with diabetes mellitus ; patient with autoimmune disease ; hypersensitivity to silymarin ; using anti inflammatory drugs or other antioxidant ; patient disagreement

Intervention groups
Intervention group: prescribing of Silymarin oral solution (140mg silymarin/cc) four times a day and each time 1cc after meal to patient with non metastatic prostate cancer after radical prostatectomy and Placebo group: prescribing of 1 cc placebo solution with same appearance only without effective ingredient after meal, four times a day to patient with non metastatic prostate cancer after radical prostatectomy

Main outcome variables
Basic Prostate specific antigen plasma level ; testosterone and Sex hormone binding globulin plasma level ; Insulin like growth factor_1 plasma level; quality of life ; hepatic transaminases ; serum creatinine ; blood urea nitrogen; side effects especially digestive complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180517039694N1**
Registration date: **2018-06-13, 1397/03/23**
Registration timing: **prospective**

Last update: **2018-06-13, 1397/03/23**
Update count: **0**

Registration date
2018-06-13, 1397/03/23

Registrant information

Name
Ashkan Fatemi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluating the effect of oral nano formulation of silymarin in non metastatic prostate cancer patients after radical prostatectomy

Public title
Efficacy of oral silymarin formulation on prostate cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Intermediate_risk prostate cancer with gleason score<8 Life expectancy more than 10 years
Exclusion criteria:
Patient with history of chemotherapy,radiotherapy or hormone therapy Patient with chronic liver or kidney or heart disease Patient with diabetes mellitus Patient with autoimmune disease History of hypersensitivity to silymarin concomitant use of anti inflammatory drugs or other antioxidant Patient disagreement
Age
From **50 years** old to **75 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization based on prepared list by randomization.com site. Then, block randomization of four patients was used to ensure balanced allocation of eligible patients in the control and intervention arms.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Silymarin and placebo nano formulations will fill by producer company and deliver to the oncologist. Patients who fulfilled the inclusion criteria will be selected by oncologist. He will assign them to silymarin or placebo group and give them bottles marked A or B, based on allocation sequence. Evaluation of patients during the chemotherapy course will be performed by the clinical oncologist and pharmacy student. Data collection and analysis will be carried out by the pharmacy student and the clinical pharmacist, respectively. All of them will not aware of the group allocation of the patients
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Ghoreishi Building, Daneshgah Street, Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
1394491388
Approval date
2018-03-17, 1396/12/26
Ethics committee reference number
IR.MUMS.REC.1396.412

Health conditions studied

1

Description of health condition studied
Non metastatic prostate cancer
ICD-10 code
D29.1
ICD-10 code description
Benign neoplasm of prostate

Primary outcomes

1

Description
Basic Prostate specific antigen serum level
Timepoint
at the beginning of the study, 2 weeks after the beginning of study, one month after the begining of the study , 6 weeks after the beginning of study and at the end of the study
Method of measurement
Serum level measurement by laboratory test

2

Description
testosterone serum level
Timepoint
At the beginning and end of the study
Method of measurement
Serum level measurement by laboratory test

3

Description

Sex hormone binding globulin serum level

Timepoint

At the beginning and the end of the study

Method of measurement

Serum level measurement by laboratory test

4

Description

Insulin-like growth factor-1 serum level

Timepoint

At the beginning and the end of the study

Method of measurement

Serum level measurement by laboratory test

5

Description

Patient quality of life

Timepoint

At the end of the study

Method of measurement

Expanded Prostate Cancer Index Composite

Secondary outcomes

1

Description

Serum level of hepatic transaminases

Timepoint

At the beginning of the study and after one and two month

Method of measurement

Serum level measurement by laboratory test

2

Description

creatinine Serum level

Timepoint

At the beginning of the study and after one and two month

Method of measurement

Serum level measurement by laboratory test

3

Description

Blood urea nitrogen

Timepoint

AT the beginning of the study and after one and two month

Method of measurement

Serum level measurement by laboratory test

Intervention groups

1

Description

Intervention group: 140mg silymarin/cc four times a day and each time 1cc after meal,oral, for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: placebo for silymarin four times a day and each time 1cc after meal,oral, for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital, affiliated to Mashhad University of Medical Sciences

Full name of responsible person

Sepideh Elyasi

Street address

School of Pharmacy, Ferdowsi University campus, Vakil Abad Blvd., Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Ashkan Fatemi Shandiz

Position
Pharm D student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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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
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 mentioned data will be published in an article after the completion of the study.

When the data will become available and for how long
The information will be available in article for ever.

To whom data/document is available
any one who want

Under which criteria data/document could be used
Unpublished data will be accessible after agreement of all contributors and also research deputy of Mashhad

University of Medical Sciences.

From where data/document is obtainable

Mail to the corresponding author

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

The request should be discussed with all contributors of the study and research deputy of Mashhad University of Medical Sciences.

Comments