Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Evaluation of the effect of zinc supplementation in treatment of patients with chronic pelvic pain syndrome

Protocol summary

Study aim
Evaluation of the effect of zinc supplementation in the treatment of patients with chronic pelvic pain syndrome
Design
A clinical trial with the control group, phase 2-3 is performed on 60 patients with parallel groups to evaluate the effect of zinc supplementation on pelvic floor pain.
Settings and conduct
This study is performed in Shahid Beheshti Hospital. Patients with chronic pelvic pain will be treated with either a zinc supplement or a placebo, and the amount of pelvic pain before and after treatment will be compared.
Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18-65 years, diagnosis of chronic pelvic pain syndrome by a urologist, absence of underlying disease, free and informed written consent
Exclusion criteria: failure to take medication regularly, drug intolerance, taking zinc supplements during the last three months, and tendency to leave during the study
Intervention groups
Intervention group: Patients in this group, in addition to routine medications, will be treated with 30 mg of zinc supplements on a daily basis for one month. Control group: Patients in this group will receive placebo tablets daily for one month in addition to routine medications. Before the interventions, after two weeks and one month, the patients' pain and their chronic pelvic pain will be measured and compared by a questionnaire.
Main outcome variables
Pain, chronic pelvic pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210614051574N12**
Registration date: **2022-06-22, 1401/04/01**
Registration timing: **prospective**

Last update: **2022-06-22, 1401/04/01**
Update count: **0**
Registration date
2022-06-22, 1401/04/01

Registrant information
Name
Ghasem Mohammadsharifi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-07-22, 1401/04/31
Expected recruitment end date
2022-09-05, 1401/06/14
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of zinc supplementation in treatment of patients with chronic pelvic pain syndrome

Public title
Zinc supplementation and chronic pelvic pain syndrome
Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18-65 years Diagnosis of chronic pelvic pain syndrome by a urologist Absence of underlying disease Free and informed written consent

Exclusion criteria:

Failure to take medication regularly Drug intolerance Taking zinc supplements during the last 3 months Tendency to leave during the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Each participant's name and type of intervention (placebo or zinc sulfate) are written on a piece of paper and enclosed in an envelope. The envelopes containing the names of the participants will be placed in one box, and the envelopes containing the type of intervention will be placed in the other box. An uninformed person first picks up an envelope from the first box and then from the second box and gives it to the study coordinator. The coordinator writes down the participant's name and the selected intervention type. The process continues until all boxes are emptied.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study uses a placebo similar to zinc tablets that have similar appearance properties. Patients are not aware of the type of substances they receive and are unaware of their intervention type. Also, health care providers and evaluators of the results of interventions do not know the patient groups and the type of medication received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh St.

City

Hamadan

Province

Hamadan

Postal code

6516719657

Approval date

2022-05-06, 1401/02/16

Ethics committee reference number

IR.UMSHA.REC.1401.132

Health conditions studied

1

Description of health condition studied

Chronic pelvic pain syndrome

ICD-10 code

R10.2

ICD-10 code description

Pelvic and perineal pain

Primary outcomes

1

Description

Pain

Timepoint

Before and after two weeks and one month after interventions

Method of measurement

Visual analog scale

2

Description

Chronic pelvic pain

Timepoint

Before and after two weeks and one month after interventions

Method of measurement

Chronic Prostatitis Symptom Index (NIH-CPSI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group, in addition to routine medications, treated with zinc supplements (made by Abian Company, containing 41.4 mg of zinc sulfate) will take daily intake for 1 month. Before the

interventions, after 2 weeks and 1 month, the amount of pain and chronic pelvic pain will be measured and compared by a questionnaire.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will receive placebo tablets daily for one month in addition to routine medications. Before the interventions, after two weeks and one month, the patients' pain and their chronic pelvic pain will be measured and compared by a questionnaire.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamedan Shahid Beheshti Hospital

Full name of responsible person
Mahdi Vanaie

Street address
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6517953371

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Reza Shokoohi

Street address
4th Floor, Hamedan University of Medical Sciences Headquarters, Shahid Fahmideh St., Pajouhesh Sq.

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reza.shokohi@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Behruz Karkhanei

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Urology

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Person responsible for updating data

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mahdi Vanaie

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Urology

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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

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Website of the Research Committee of Hamedan University of Medical Sciences

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments