

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of intra-lesion injection of vitamin D3 versus cryotherapy on the treatment of plantar warts: a randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of intra-lesion injection of vitamin D3 versus cryotherapy on the treatment of plantar warts

##### Design

This is a randomized clinical trial, phase II, in which 192 eligible patients will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible patients with plantar warts referring to the Sina Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years, Plantar warts,  
Exclusion criteria: Pregnancy or breastfeeding, Immunodeficiency syndrome, Presence of wound or infection or active dermal lesion on the plantar area, History of convulsion

##### Intervention groups

Intervention group: Intra-lesion injection of vitamin D3 0.75 mg every 3 weeks for 3 times plus topical ointment zinc oxide 1% twice daily for 2 weeks  
Control group: Cryotherapy of the wart for 20 second every 2 weeks for 5 times plus topical ointment zinc oxide 1% twice daily for 2 weeks

##### Main outcome variables

Primary outcome: Improvement of plantar wart  
Secondary outcome: Side effects including pain, erythema, swelling, and pigmentation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N358**

Registration date: **2020-06-08, 1399/03/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-08, 1399/03/19**

Update count: **0**

##### Registration date

2020-06-08, 1399/03/19

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-04, 1399/02/15

##### Expected recruitment end date

2021-05-05, 1400/02/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of intra-lesion injection of vitamin D3 versus cryotherapy on the treatment of plantar warts: a randomized clinical trial

##### Public title

Effect of intra-lesion injection of vitamin D3 versus cryotherapy on the treatment of plantar warts

##### Purpose

Treatment

IR.UMSHA.REC.1399.221

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Age of 18 to 65 years, Plantar warts,

### **Exclusion criteria:**

Pregnancy or breastfeeding, Immunodeficiency syndrome, Presence of wound or infection or active dermal lesion on the plantar area History of convulsion

## **Age**

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

## **Gender**

Both

## **Phase**

2

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **192**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

## **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**

Ethics Committee of Hamadan University of Medical Sciences

##### **Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### **City**

Hamadan

##### **Province**

Hamadan

##### **Postal code**

6517838695

#### **Approval date**

2020-05-23, 1399/03/03

#### **Ethics committee reference number**

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Plantar wart

#### **ICD-10 code**

B07.0

#### **ICD-10 code description**

Plantar wart

## **Primary outcomes**

### 1

#### **Description**

Improvement of plantar wart

#### **Timepoint**

Every 3 weeks in the intervention group and every 2 weeks in the control group for 2 months

#### **Method of measurement**

With physical examination

## **Secondary outcomes**

### 1

#### **Description**

Side effects including pain, erythema, swelling, and pigmentation

#### **Timepoint**

Every 3 weeks in the intervention group and every 2 weeks in the control group for 2 months

#### **Method of measurement**

with physical examination

## **Intervention groups**

### 1

#### **Description**

Intervention group: Intra-lesion injection of vitamin D3 0.75 mg every 3 weeks for 3 times plus topical ointment zinc oxide 1% twice daily for 2 weeks

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Cryotherapy of the wart for 20 second every 2 weeks for 5 times plus topical ointment zinc oxide 1% twice daily for 2 weeks

#### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Sina Hospital in Hamadan city

**Full name of responsible person**

Dr Shima Baniardalan

**Street address**

Sina Hospital, Mirzadeh Eshghi Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3827 4184

**Email**

shima\_ba@hotmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0717

**Email**

info.research@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**

Dr Shima Baniardalan

**Position**

Resident of Dermatology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

6517838695

**Email**

shima\_ba@hotmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Reza Sobhan

**Position**

Dermatologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

**Street address**

School of Medicine, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0572

**Email**

mreza\_sobhan@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available