

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