Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of calcipotriol ointment in the treatment of cutaneous wart

Protocol summary

Study aim
The effect of calcitriol ointment on the treatment of skin warts

Design
Two arm parallel-group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
This study is a randomized controlled clinical trial and all patients with cutaneous warts referred to dermatology clinic of Bu Ali Sina Hospital in Sari during the years 98 to 99 with inclusion criteria and excluding exclusion criteria were included. Individuals' personal information including age, sex, number of lesions, duration of the lesion is recorded in the questionnaire by the designers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with cutaneous warts that are diagnosed by a dermatologist clinically or pathologically and need treatment. - Over 4 years old - Informed consent to enter the study -The number of warts up to 20 Exclusion criteria: - Children under 2 years, pregnant and lactating women - Patients who are contraindicated for calcipotriol treatment. - Facial genital warts - Patients who do not consent to participate in the study. - People who are allergic to topical vitamin D derivatives. - Widespread warts that need further treatment.

Intervention groups
Intervention group: 0.005% calcitriol ointment in addition to the routine treatment twice daily (every 12 hours) is applied by the patient or his / her parents on the lesions so that the ointment with a thickness of one millimetre is applied on the lesion surface. Control group: Only receive routine treatment.

Main outcome variables
Response to treatment is considered complete response, partial improvement (reduction in the number and in individual lesions size reduction) as of measurement and expression of percentage and no improvement, and 4 months after complete recovery of the patient, recurrence of lesions is examined.

General information

Reason for update
typographical mistakes

Acronym

IRCT registration information
IRCT registration number: **IRCT20170818035762N2**
Registration date: **2020-02-17, 1398/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-30, 1399/07/09**
Update count: **1**

Registration date
2020-02-17, 1398/11/28

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 4221 8021
Email address
a.kazeminejad@mazums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of calcipotriol ointment in the treatment of

cutaneous wart

Public title
The effect of calcitriol ointment on skin warts
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with cutaneous warts that are clinically or pathologically diagnosed by a dermatologist and need treatment The number of warts up to 20 Minimum enrollment age is 4 years
Exclusion criteria:
People who are allergic to topical vitamin D derivatives. Warts that need further treatment.
Age
From **4 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
First, according to the inclusion criteria, 56 patient will be selected by the available sampling method. Then, this 56 patient will be assigned to 2intervention and control groups. The blocking process will be done with the Rando allocation software. This software will create 14 blocks containing 4 patient and the samples will be grouped accordingly.
Blinding (investigator's opinion)
Double blinded
Blinding description
Blinding in this study will be done like this the intervention group will receive routine treatment in addition to calcitriol ointment and the control group will receive only routine treatment. The researcher, patient, and individual analyzer will not be aware of the type of medication prescribed by the physician.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Vice chancellor for research.University Building number2 .Moalem Square.Sari
City
sari
Province
Mazandaran
Postal code
۴۸۱۵۷۳۳۹۷۱
Approval date
2020-01-05, 1398/10/15
Ethics committee reference number
IR.MAZUMS.REC.1398.1259

Health conditions studied

1

Description of health condition studied
Skin warts
ICD-10 code
B07
ICD-10 code description
Viral warts

Primary outcomes

1

Description
Response to treatment is considered complete response, relative improvement (reduction in number and size reduction in individual lesions) as measurement and expression of percentage and no improvement.
Timepoint
The patient is examined monthly by a dermatologist
Method of measurement
Based on clinical examination of dermatologist

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 0.005% calcipotriol ointment in addition to the routine treatment twice daily (every 12 hours) is applied by the patient or his / her parents on the lesions, so that the ointment with a thickness of one millimeter is applied on the lesion surface. . The patient is visited by a physician on a monthly basis the number and size of lesions, complications such as erythema and scaling around the lesion, pain, worsening of the lesions,

and other associated symptoms. Treatment is continued for 2 months and if not treated for up to 4 months.

Category

Treatment - Drugs

2

Description

Control group: This group will only receive routine treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Bou Ali Hospital

Full name of responsible person

Dr.Armaghan Kazeminejad

Street address

Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Jouybar Road.Sari

City

Sari

Province

Mazandaran

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۳۳۹۷۱۴۸۱۵۷

Phone

+98 11 3304 4001

Email

publicrel@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeedi

Street address

Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari

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Grant name

Grant code / Reference number

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

No

Title of funding source

No

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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.ArMarghan Kazeminejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari

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Postal code

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Armarghan KazemiNejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact
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Full name of responsible person
Dr Armaghan Kazeminejad
Position
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Latest degree
Specialist
Other areas of specialty/work
Dermatology
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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
No - There is not 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
Yes - There is 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
Title and more details about the data/document
Only part of the data, such as information about the main outcome or the like, can be shared
When the data will become available and for how long
Start of access period 6 months after stablishing results
To whom data/document is available
It will only be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
It will only be available to researchers working in academic and scientific institutions
From where data/document is obtainable
Email to: A.kazeminejad@mazums.ac.ir
What processes are involved for a request to access data/document
After communicating with the email if available, data and results will be available
Comments