Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of the effects of vitamin D3 (cholecalciferol) ointment on atopic eczema in patients 2-18 years old

Protocol summary

Study aim

The aim of this study is to evaluate the effect of topical cholecalciferol in mild to moderate atopic eczema in patients aged 2 to 18 years.

Design

To compare the effect of the drug and the placebo, after determining the blood level of vitamin D, the patients will be divided into three groups of a least 10 persons: 1) Patients with vitamin D deficiency who receive oral vitamin D and ointment containing drug. 2) Patients who lack vitamin D deficiency are divided into two groups of drugs and placebo in two-blinded and randomized (using random sequences) models. From the time of admission to study, patients should use topical vitamin D 1,000 units per gram and placebo once a day for 8 weeks. Patients are required to refer to follow-up times at specified times (0,4,8) and after 8 weeks, photos and EASI are recorded.

Settings and conduct

Patients refer to Skin and Stem Cell Research Center and Children Medical Center Hospital, after determining the blood level of vitamin D, will divide into three groups of at least 10 persons: 1) Patients with vitamin D deficiency who receive oral vitamin D and ointment containing drug. 2) Patients who lack vitamin D deficiency are divided into two groups of drugs and placebo in two-blinded and randomized (using random sequences) models. From the time of admission to study, patients should use topical vitamin D 1,000 units per gram and placebo once a day for 8 weeks. Patients are required to refer to follow-up times at specified times (0,4,8) and after 8 weeks, photos and EASI are recorded.

Participants/Inclusion and exclusion criteria

inclusion criteria: 1) aged 2-18 in both genders 2) discontinuation of topical treatment at least 2 weeks ago and for patients who use systemic therapy, it should be stable for months (at least 2 months) and plaque lesions remain in the use of systemic therapy. 3) mild to moderate eczema; Exclusion criteria: 1) History of allergy to the compounds in the formulation and vitamin D3 derivatives 2) aged over 18 years 3) Hypervitaminosis D 4) hypercalcemia 5) Patients with acute eczema attack 6) The presence of skin infection or malignancy at the treatment site 7) The presence of diseases associated with vitamin D metabolism disorders

Intervention groups

Patients in the intervention group should use cholecalciferol 1000 unit per gram ointment once a day for 8 weeks on lesions. Patients in the control group should use a drug-free ointment once a day for 8 weeks on lesions. The placebo ointment contains 95% vaseline and 5% bee wax

Main outcome variables

1) Quality of Life 2) Eczema severity 3) adverse effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100119003106N36**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

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Recruitment status
Recruitment complete
Funding source
investigator

Expected recruitment start date
2017-05-22, 1396/03/01
Expected recruitment end date
2018-05-22, 1397/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of the effects of vitamin D3 (cholecalciferol) ointment on atopic eczema in patients 2-18 years old

Public title
Assessment of the effect of cholecalciferol ointment on atopic eczema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
aged 2-18 in both genders discontinuation of topical treatment at least 2 weeks ago and for patients who use systemic therapy, it should be stable for months (at least 2 months) and plaque lesions remain in the use of systemic therapy mild to moderate eczema
Exclusion criteria:
History of allergy to the compounds in the formulation and vitamin D3 derivatives aged over 18 years Hypervitaminosis D hypercalcemia Patients with acute eczema attack The presence of skin infection or malignancy at the treatment site The presence of diseases associated with vitamin D metabolism disorders
Age
From **2 years** old to **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
This study was designed simple randomization method using random numbers table.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients with vitamin D in excess of 30 ng/ml received ointment and placebo in two-blinded manner. The ointments are coded by the Pharmaceutical Department of the College of Pharmacy (a and b) and the researcher, physicians, and patients do not know the contents of ointment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University Of Pharmaceutical Sciences Branch
Street address
Islamic Azad University Of Pharmaceutical Sciences Branch,Yakhchal avenue,Shariati
City
Tehran
Province
Tehran
Postal code
193956466
Approval date
2017-01-05, 1395/10/16
Ethics committee reference number
IR.IAU.PS.REC.1395.48

Health conditions studied

1

Description of health condition studied
Atopic dermatitis
ICD-10 code
L20.9
ICD-10 code description
Atopic dermatitis, unspecified

Primary outcomes

1

Description
Quality of Life
Timepoint
beginning of the treatment, 4 weeks and 8 weeks after starting the treatment
Method of measurement
questionnaire

2

Description
Eczema severity
Timepoint
beginning of the treatment, 4 weeks and 8 weeks after starting treatment
Method of measurement
EASI

Secondary outcomes

1

Description
adverse effect
Timepoint
beginning of the treatment, 4 weeks and 8 weeks after starting treatment
Method of measurement
physician assessment

Intervention groups

1

Description
Patients in the control group should use a drug-free ointment once a day for 8 weeks on lesions.The placebo ointment contains 95% vaseline and 5% bee wax.
Category
Placebo

2

Description
Patients in the intervention group should use cholecalciferol 1000 unit per gram ointment once a day for 8 weeks on lesions.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Skin and Stem Cell Research Center
Full name of responsible person
Dr Parvin Mansouri
Street address
No 4 Maryam Dead End South Andarzgo Blvd, Kamraniyeh, Tehran
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2

Recruitment center
Name of recruitment center
Children Medical Center Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pharmaceutical Sciences branch, Islamic Azad University
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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
Pharmaceutical Sciences branch, Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University Of Pharmaceutical Sciences Branch
Full name of responsible person
Rayeheh Tavajjohi
Position
Student of pharmacy
Latest degree
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Person responsible for updating data

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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
Not applicable
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