

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Effectiveness of vitamin D in Treg cell frequency in atopic dermatitis and control group

Protocol summary

Study aim

Aim of this study was evaluating the effects of vitamin D in patients with atopic dermatitis, and assessing its efficacy and capability on immune response modulating.

Design

The Clinical trial with community-based and pragmatic control group, parallel groups, randomized with number table. not blinded and the intervention was conducted in Phase 3 on 20 subjects in each group (intervention and control) for 2 months, they gave one tablet or drops of vitamin D1000 units daily.

Settings and conduct

This study was conducted on the effect of vitamin D in controlling atopic dermatitis in patients with vitamin D deficiency who referred to the Allergy clinic of Ghaem Hospital of Mashhad University of Medical Sciences and compared with control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients up to 50 years old who have clinical signs of atopic dermatitis 2. Low serum vitamin D levels 3. No oral drug for controlling atopic dermatitis recently Exclusion criteria: 1- Patients with other atopic diseases 2 Having skin infections

Intervention groups

In the case group, 20 patients with atopic dermatitis with vitamin D deficiency (<30 mg/dl) were given daily for 2 months a tablet or drops of vitamin D1000 unit with the combination of 1-alpha-hydroxycholecalciferol from Vitabothic company . In the control group, 20 people without allergy and skin disease with a shortage of vitamin D (less than 30 mg / dl) received daily for 2 months a pill or drops of vitamin D1000 unit with the combination of 1-alpha-hydroxycholecalciferol from the Vitabothic company .

Main outcome variables

Changing the clinical symptoms of patients with atopic dermatitis based on scorad questionnaire and changes in the frequency of T reg cells in the peripheral blood by flow cytometry

General information

Reason for update

Acronym

درماتیک آتوپیک

IRCT registration information

IRCT registration number: **IRCT20150716023235N13**

Registration date: **2018-11-02, 1397/08/11**

Registration timing: **retrospective**

Last update: **2018-11-02, 1397/08/11**

Update count: **0**

Registration date

2018-11-02, 1397/08/11

Registrant information

Name

Farahzad Jabbari Azad

Name of organization / entity

Allergy Research Center, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 1801 2770

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jabbarif@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-02, 1396/06/11

Expected recruitment end date

2018-03-17, 1396/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Effectiveness of vitamin D in Treg cell frequency in atopic dermatitis and control group

Public title

Evaluation of Effectiveness of vitamin D on immunity of atopic dermatitis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients up to 50 years old who have clinical signs of atopic dermatitis Low serum vitamin D levels No oral drug for controlling atopic dermatitis recently

Exclusion criteria:

Patients with other atopic diseases Having skin infections

Age

From **1 month** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization method with random number table was used.

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 Mashhad University of Medical Sciences

Street address

Ghoreishi building, Daneshgah AVE

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2017-12-20, 1396/09/29

Ethics committee reference number

IR.MUMS.fm.REC.1396.607

Health conditions studied

1

Description of health condition studied

Atopic dermatitis

ICD-10 code

L20.8

ICD-10 code description

Other atopic dermatitis

Primary outcomes

1

Description

Clinical symptoms of atopic dermatitis

Timepoint

At the beginning of the study (before the intervention) and 2 months after the start of the consumption

Method of measurement

SCORAD questionnaire

2

Description

Frequency of T reg cells in the blood

Timepoint

At the beginning of the study (before the intervention) and 2 months after the start of the consumption

Method of measurement

Flowcytometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For patients with atopic dermatitis, for a period of 2 months, one tablet or drops of vitamin D1000 unit was given by the combination of 1-alpha-hydroxycholecalciferol from Vitabothix company.

Category

Treatment - Drugs

2

Description

Control group: 20 healthy people from the point of allergies, atopy and skin diseases received one tablet or drops of vitamin D1000 unit for 2 months, from the combination of 1-alpha-hydroxycholecalciferol from Vitabothix company.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Allergy clinic of Ghaem Hospital

Full name of responsible person

Farahzad Jabbari Azad

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Central Building of Mashhad University of Medical Sciences (Ghoreishi), Daneshgah 16, Daneshgah street

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Payam Payandeh

Position

Non-faculty specialist

Latest degree

Specialist

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Latest degree

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available