

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study the effect of vitamin D on the activity of T-regulator cell and Th17 and its association with clinical symptoms of patients with idiopathic chronic urticaria

Protocol summary

Summary

The aim of this study was to evaluate the effect of vitamin D in the treatment of chronic idiopathic urticaria and its immunological changes. This pilot trial was performed on 20 patients with chronic idiopathic urticaria before and after treatment without any control group. Chronic idiopathic urticarial patients with rejection of other possible causes of chronic urticaria by interview, allergy test and blood test with serum level 25 OH vit D less than 10 ng / ml enter the trial. The study was conducted with the help of an allergist and PhD Immunology as a single center of the Allergy Clinic of Ghaem Hospital in Mashhad. This study has been done in Phase 3 and not blinded inclusion Criteria are getting chronic urticaria scheme more than 6 weeks, rejection of allergenes, patient satisfaction, and serum levels of 25 OH vit D should be less than 10 ng / ml, and exclusion criteria are the presence of various types of allergic diseases in the patient, corticosteroid drug usage, Autoimmune and immunodeficiency disease, normal levels of vitamin D. The main Outcome are assessment the quality of life with DLQI questionnaire, idiopathic urticaria severity based on USS questionnaire, TGF- β gene expression, IL-10 gene expression, IL-17 gene expression , FOXP3 gene expression

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017092123235N12**
Registration date: **2017-10-24, 1396/08/02**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-24, 1396/08/02

Registrant information

Name

Farahzad Jabbari Azad

Name of organization / entity

Allergy Research Center, Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1801 2770

Email address

jabbarif@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of vitamin D on the activity of T-regulator cell and Th17 and its association with clinical symptoms of patients with idiopathic chronic urticaria

Public title

Study the effect of vitamin D on the symptoms of urticaria

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: Chronic urticaria affected for more than 6 weeks, negative skin Prick test for common respiratory allergens. Patient's willingness to take medication and participate, The serum level of 25 OH vit D Should be less than 10 ng / ml Exclusion criteria: taking Corticosteroid drug during the past week. having Other allergic diseases and Infectious diseases and Autoimmune disease Normal levels of vitamin D

Age
 No age limit

Gender
 Both

Phase
 3

Groups that have been masked
No information

Sample size
 Target sample size: 20

Randomization (investigator's opinion)
 N/A

Randomization description

Blinding (investigator's opinion)
 Not blinded

Blinding description

Placebo
 Not used

Assignment
 Single

Other design features
 The trial phase is 3 as this project worked on human subjects

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashahd University of Medical Sciences

Street address

Ghoreish building, Daneshgah Street

City

Mashhad

Postal code

Approval date

2013-09-11, 1392/06/20

Ethics committee reference number

IR.MUMS.REC.1392.154

Health conditions studied

1

Description of health condition studied

Idiopathic chronic urticaria

ICD-10 code

L50.8

ICD-10 code description

Other urticaria

Primary outcomes

1

Description

Quality of life

Timepoint

Before the trial

Method of measurement

DLQI Questionnaire

2

Description

Urticaria severity

Timepoint

Before the trial

Method of measurement

USS Questionnaire

Secondary outcomes

1

Description

IL-17 Expression

Timepoint

After the trial

Method of measurement

Real-time PCR

2

Description

IL-10 Expression

Timepoint

After the trial

Method of measurement

Real-time PCR

3

Description

TGF-β Expression

Timepoint

After the trial

Method of measurement

Real-time PCR

4

Description

Foxp3 expression

Timepoint

After the trial

Method of measurement

Intervention groups

1

Description

every 10 days, 1 tablet of 50,000 units of vitamin D is given to the patient.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy Clinic Ghaem Hospital

Full name of responsible person

Reza Farid Hosseiny

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr.Mohsen Tafaghodi

Street address

Ghoreishi Building, Daneshgah Ave, mashhad

City

Mshhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Shima Zarei

Position

Msc of Immunology

Other areas of specialty/work

Street address

Department of Immunology and Allergy, Hospital Ghaem, Ahmadabad streets, Mashhad

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad university of medical sciences

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Farahzad Jabbari Azad

Position

subspecialist of Immunology and Allergy

Other areas of specialty/work

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Person responsible for updating data

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Reza Farid Hosseiny

Position

Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty