Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Aliergy 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 utricaria 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
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Iran (Islamic Republic of)
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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

Befor the trial

Method of measurement

DLQI Questionnaire

2

Description

Utricaria severity

Timepoint

Befor the trial

Method of measurement

USS Questionnaire

Secondary outcomes

1

Description

IL-17 Exprssion

Timepoint

After the trial

Method of measurement

Real-time PCR

2

Description

IL-10 Exprssion

Timepoint

After the trial

Method of measurement

Real-time PCR

3

Description

TGF-B Expression

Timepoint

After the trial

Method of measurement

Real-time PCR

4

Description

Foxp3 expression

Timepoint

After the trial

Method of measurement

Real-time PCR

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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Reza Farid Hosseiny
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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