Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Evaluation of the effect of colchicine on the antithyroid antibody titer in chronic urticaria patient.

Protocol summary

Study aim
Determination of serum levels of Anti TPO and Anti Tg before starting treatment and 3 month after starting treatment with Colchicine in chronic urticaria patients
Record information about patient examinations based on the UAS7 and CU_Q2oL questionnaire before starting treatment and 3 month after starting treatment with Colchicine in chronic urticaria patients

Design
A double blind randomized clinical trial with parallel groups

Settings and conduct
50 patients with chronic urticaria will be considered as the study population referred to the allergy clinic of Imam Reza Clinic in Shiraz. Informational examinations of patients based on 2 standard questionnaires CU_Q2oL and UAS with questioner will be recorded in 2 steps (before the intervention, and 3 months after the intervention). Then, blood samples are taken from all patients with chronic urticaria , including Anti-TPO and Anti-TG serum levels (before the intervention, and 3 months after the intervention). Patients were randomly assigned to 2 groups based on their case number was even or odd, control group (standard treatment, including Fexofenadine and Doxepin) and the intervention group (including standard treatment + oral Colchicine at a dose of 1 mg daily for 3 months). The results will be recorded and finally compared with the results before the intervention.

Participants/Inclusion and exclusion criteria
Including patients with chronic urticaria with positive thyroid autoantibodies in the age range of 20 to 70 years ; excluding below 20 age, pregnant and lactating women, side effect of Colchicine

Intervention groups
The control group is treated with Fexofenadine and Doxepin for 3 months. The intervention group will receive Fexofenadine, Doxepin and Colchicine 1 mg for three months.

Main outcome variables
Reducing the title of autoantibodies and the symptoms of patients with urticaria after treatment with Colchicine

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200406046967N1**
Registration date: **2020-04-10, 1399/01/22**
Registration timing: **prospective**

Last update: **2020-04-10, 1399/01/22**
Update count: **0**

Registration date
2020-04-10, 1399/01/22

Registrant information
Name
Masroor Babaeian
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-05-04, 1399/02/15
Expected recruitment end date
2020-08-05, 1399/05/15
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of colchicine on the antithyroid antibody titer in chronic urticaria patient.

Public title

Effect of Colchicine in treatment of chronic urticaria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic urticaria in the age range of 20 to 70 years

Exclusion criteria:

pregnant and lactating females Patients with Physical Urticaria and Vasculitis Urticaria Patients with Colchicine-induced drug side effects

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is based on a Random number table. In this study, table numbers are read from above and to the right. Couples' numbers are for the first group (intervention) and individual numbers are for the second group (control).

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients know that they are participating in the study and have entered the study consciously and with prior written consent, but do not know exactly which group they are in. he main researchers of the study are unaware of the type of medication used for each patient and how the patients are assigned to the groups and which group each patient is in. Data collection and follow-up officials are unaware of the type of medication used for each patient and how the patients are assigned to the groups and which group each patient is in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

3rd floor., Niki 2 building., Ansar Ave., besat Blvd

City

Shiraz

Province

Fars

Postal code

7184684189

Approval date

2019-09-08, 1398/06/17

Ethics committee reference number

IR.SUMS.Med.Rec.1398.390

Health conditions studied

1

Description of health condition studied

Positive Autoantibody Chronic Urticaria

ICD-10 code

L50.1

ICD-10 code description

Idiopathic urticaria

Primary outcomes

1

Description

"Percentage of people with chronic urticaria who have autoimmune thyroiditis"

Timepoint

"Measurement of thyroid autoantibodies at the beginning of the study (before the intervention) and 3 months after taking colchicine"

Method of measurement

"Peripheral blood sample"

Secondary outcomes

1

Description

" The urticaria score in the Urticaria Activity Score 7 questionnaire"

Timepoint

" Comparison of the average total score of the Urticaria Activity Score 7 questionnaire in the study groups at the beginning of the study and 3 months after taking colchicine"

Method of measurement
" Urticaria Activity Score 7 questionnaire"

2

Description
"The urticaria score in the Chronic Urticaria Quality of Life questionnaire"
Timepoint
Comparison of the average total score of the Chronic Urticaria Quality of Life questionnaire in the study groups at the beginning of the study and 3 months after taking colchicine"
Method of measurement
"Chronic Urticaria Quality of Life questionnaire"

Intervention groups

1

Description
Intervention group: "The first intervention group of Fexofenadine tablets 120 mg once daily for 3 months from Saha Pharmaceuticals, Doxepin tablets 10 mg once daily for 3 months from Razak Pharmaceuticals and Colchicine tablets 1 mg once daily for 3 months from Modava Pharmaceuticals"
Category
Treatment - Drugs

2

Description
Intervention group: "The second intervention group of Fexofenadine tablets 120 mg once daily for 3 months from Saha Pharmaceuticals, Doxepin tablets 10 mg once daily for 3 months from Razak Pharmaceuticals" ;
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Clinic
Full name of responsible person
Masroor Babaeian
Street address
Imam Reza Specialized and Subspecialty Clinic, next to Namazi Hospital, Namazi Square
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motahari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Hesam Nabavi Zadeh
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Pediatric's Department Office, Namazi Hospital, Namazi Square
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Masroor Babaeian
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after people have not been identified.
When the data will become available and for how long
Starting the access period 3 months after the publication of the results
To whom data/document is available
It will be available for researchers worker in academic and scientific institutions.
Under which criteria data/document could be used
they can provide jobs, university and reason of using data and articles.
From where data/document is obtainable
Email adress
What processes are involved for a request to access data/document
2 days
Comments