

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the therapeutic effects of Mesalazine in patients with chronic idiopathic urticaria

Protocol summary

Summary

The Goal of this open clinical trial is to evaluate the effect of Mesalazine on Chronic Idiopathic Urticaria. 30 patients are selected randomly. The patients include new cases and resistant cases to Antihistamines. We exclude children under 12 years old, pregnant and breastfeeding mothers, those with sensitivity to this medication and those with underlying problems. After performing CBC, LFT, BUN, Cr, Stool Exam and TFT, Mesalazine 500 mg Bid is administered to the patients and they would be followed after 15 and 60 days. The primary outcome is decrease in symptoms and improvement in quality of life of the patients according to the indices recorded. If any improvement observed in first 15 days of treatment, the drug would be discontinued.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138710041520N1**

Registration date: **2009-04-03, 1388/01/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-04-03, 1388/01/14

Registrant information

Name

Alireza Abdollahee

Name of organization / entity

Shiraz University Of Medical Sciences , Dermatology
Department

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research of Shiraz University of
Medical Sciences

Expected recruitment start date

2008-06-26, 1387/04/06

Expected recruitment end date

2009-05-22, 1388/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effects of Mesalazine in
patients with chronic idiopathic urticaria

Public title

Mesalazine in chronic idiopathic urticaria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: new cases, the patients without proper
control with antihistamines Exclusion Criteria : children
under 12y, pregnant ladies or women with breast
feeding, underlying diseases, 5-ASA sensitivity, G6PD
deficiency

Age

From **12 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

30 patients with chronic idiopathic urticaria for more than 6 weeks, without any etiologic finding in lab tests and examinations, include in the research.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University Of medical sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Postal code

Approval date

2008-06-24, 1387/04/04

Ethics committee reference number

2954

Health conditions studied

1

Description of health condition studied

Chronic Idiopathic urticaria

ICD-10 code

L50.1

ICD-10 code description

Idiopathic Urticaria

Primary outcomes

1

Description

Decrease in Symptoms of the patients

Timepoint

15 days and 1 month and 2 month

Method of measurement

Symptom Severity indices and Quality of Life

Questionnaire

Secondary outcomes

1

Description

Improvement in Quality of Life of the patients

Timepoint

2 month

Method of measurement

Quality of life Questionnaire

Intervention groups

1

Description

Mesalazine 500 mg Bid for 2 months

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinics - Shiraz Faghihi Hospital

Full name of responsible person

Street address

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences - Vice Chancellor for Research Affairs

Full name of responsible person

Dr. Mohammad Hosein Dabaghmanesh

Street address

Central Bulding Of Shiraz University Of Medical Sciences- Vice Chancellor for Research Affairs - Zand Street

City

Shiraz

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 - Vice Chancellor for Research Affairs

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**

Shiraz University of Medical Sciences

Full name of responsible person

Alireza Abdollahee

Position

Resident of Dermatology

Other areas of specialty/work**Street address**

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Shiraz University of Medical Sciences

Full name of responsible person

Ladan Dastgheib

Position

Associate Professor of Shiraz University of Medical Sciences

Other areas of specialty/work**Street address**

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Web page address**Person responsible for updating data****Contact****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