

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Therapeutic efficacy of atorvastatin in chronic idiopathic urticaria

Protocol summary

Summary

The aim of this study is to compare the efficacy of Atorvastatin in chronic idiopathic urticaria. A total of forty seven patients between 15 to 45 years old are enrolled into the study. The patients are assigned into one of the following groups. The patients in the first group receive one Atorvastatin tablet (40 mg/Kg) and antihistamine every 12 hours and in the second group receive one placebo tablet and antihistamine every 12 hours for 3 months. Changes in autologus test and urticaria severity score are measured at the baseline and the end of treatment and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110033862N8**

Registration date: **2011-10-17, 1390/07/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-10-17, 1390/07/25

Registrant information

Name

Farahzad Jababri Azad

Name of organization / entity

Mashahd University of Medical Scineces

Country

Iran (Islamic Republic of)

Phone

+98 51 1843 6626

Email address

banihashemim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Council of Mashhad University of Medical Sciences

Expected recruitment start date

2010-10-21, 1389/07/29

Expected recruitment end date

2011-11-20, 1390/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Therapeutic efficacy of atorvastatin in chronic idiopathic urticaria

Public title

Therapeutic efficacy of atorvastatin in chronic idiopathic urticaria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of urticaria more than 8 weeks, Normality of thyroids assay test, Negativity of antithyroglobulin, antimicrosomal antibodies and skin prick test for inhale and oral common allergens Exclusion criteria: Addiction, Systemic and chronic diseases, Pregnancy

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
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
Central Building of Mashhad University of Medical Sciences
City
Mashhad
Postal code
Approval date
2009-08-09, 1388/05/18
Ethics committee reference number
87921

Health conditions studied

1

Description of health condition studied

Idiopathic urticaria
ICD-10 code
L50.1
ICD-10 code description
Idiopathic urticaria

Primary outcomes

1

Description

urticaria severity

Timepoint

Baseline and at the end of treatment course

Method of measurement

Urticaria severity is calculated according to Breneman et al to 4 categories; Mild, Moderate and severe

Secondary outcomes

1

Description

Cytokines Variations

Timepoint

baseline and after the treatment course

Method of measurement

Measuring selective cytokines by Eliza method in lymphocyte culture

Intervention groups

1

Description

one tablet Atorvastatin (40mg/Kg) every 12 hours (twice daily) in patient group until 3 month.

Category

Treatment - Drugs

2

Description

one tablet placebo every 12 hours (twice daily) until 3month in control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Allergy Reserach Center, Ghaem Hospital, Mashhad University of Medical Sciences
Full name of responsible person
Dr Reza Faridhosseini, Dr Pezeshkpoor, Dr Farahzad Jabbari, Dr Behzad Shakerian, Dr Rafatpanah
Street address
City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Council of Mashhad University of Medical Sciences

Full name of responsible person

Vice chancellor for research of Mashhad University of Medical Sciences, Dr Jalil Tavakol Afshari

Street address

Central Building of Mashhad University of Medical Sciences

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Research Council of 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**

Allergy Research Center, Mashhad University of Medical Sciences

Full name of responsible person

Dr Farahzad Jabbari

Position

Assistant Professor of Allergy and Clinical Immunology

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

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Hadis Yousefzadeh

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Web page address**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