

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Controlled clinical trial comparing the efficacy of autologous serum therapy and placebo on severe chronic urticaria

Protocol summary

Summary

Objective: controlled clinical study comparing the effect of autologous serum therapy and placebo in severe chronic urticaria. Inclusion criteria: patients entered the study had severe urticaria for at least 6 weeks in most of the days; not responding to antihistamines; patients who had no other systemic disease; those with negative food allergy skin test; patients without urticaria vasculitis. Exclusion criteria: patients with systemic disease; those who had positive allergy skin test with food; those who had a good response to antihistamines. The study population: patients with severe chronic urticaria. Target sample size: 50 patients. Design: Took 6 ml blood from patients and after clotting put it in Centrifuge to run with 2000 rpm for 10 minutes separating serum then inject 2.5 ml serum deeply in Deltoids muscle, in control group 2.5 ml normal saline injected instead as single blind. Intervention: weekly for 9 weeks, then monthly for 3-6 months injection were given. Time project: 2013 - 2014. Primary outcome measure: before onset of treatment and end of weekly treatment and end of monthly treatment. Patients are checked for 6 parameters.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061818137N1**

Registration date: **2015-01-25, 1393/11/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-25, 1393/11/05

Registrant information

Name

Reza Amin

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 3228 8574

Email address

aminr@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2014-01-30, 1392/11/10

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

Controlled clinical trial comparing the efficacy of autologous serum therapy and placebo on severe chronic urticaria

Public title

Assessment of effect of autologous serum therapy on severe chronic urticaria and comparison with placebo injections

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients entered the study had severe urticaria for at least 6 weeks in most of the days; not responding to antihistamines; patients who had no other systemic disease; those with negative food allergy skin

test; patients without urticaria vasculitis. Exclusion criteria: patients with systemic disease; those who had positive allergy skin test with food; those who had a good response to antihistamines.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

After selecting patients who met the before mentioned criteria and taking their informed consent they filled a questioner including: name, age , sex , local address , tell number, details of symptoms clinically in sampling. Before onset of treatment and end of 9 weekly treatment and end of monthly treatment. Patients are checked for 6 parameters. Took 6 ml blood from patients and after clotting put it in Centrifuge to run with 2000 rpm for 10 min separating serum then inject 2.5 ml serum deeply in Deltoids muscle, in control group 2.5 ml normal saline injected instead as single blind.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand street, Shiraz

City

Shiraz

Postal code**Approval date**

2014-01-21, 1392/11/01

Ethics committee reference number

CT-P-9367-6837

Health conditions studied**1****Description of health condition studied**

severe chronic urticaria

ICD-10 code

L50.1

ICD-10 code description

Idiopathic urticaria

Primary outcomes**1****Description**

Questionnaire

Timepoint

Before onset of treatment and end of weekly treatment and end of monthly treatment

Method of measurement

physical examination and history

Secondary outcomes

empty

Intervention groups**1****Description**

The injection of 2.5 ml of autologous serum for 9 weeks and then monthly for 3 to 6 months.

Category

Treatment - Drugs

2**Description**

The injection of 2.5 ml of normal saline for 9 weeks and then monthly for 3 to 6 months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Emam Reza Clinic

Full name of responsible person**Street address****City**

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

University of Medical Sciences Shiraz

Full name of responsible person
Dr.Postforosh

Street address
Zand street, Shiraz

City
Shiraz

Grant name
-

Grant code / Reference number
-

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

Title of funding source
University of Medical Sciences Shiraz

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
Farhad Abolnezhadian

Position
Fellow for Allergy and Clinical Immunology

Other areas of specialty/work

Street address
Division of Immunology, Namazi hospital, Shiraz

City
Shiraz

Postal code

Phone
+98 71 3228 8574

Fax

Email
abolnezhadian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Reza Amin

Position
Allergist and Clinical Immunologist

Other areas of specialty/work

Street address
Division of Immunology, Namazi hospital, Shiraz

City
Shiraz

Postal code

Phone
+98 71 3612 5449

Fax

Email
aminr@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Farhad Abolnezhadian

Position
Fellow for Allergy and Clinical Immunology

Other areas of specialty/work

Street address
Fars

City
Shiraz

Postal code

Phone
+98 71 3228 8574

Fax

Email
abolnezhadian@yahoo.com

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