Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 mines 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 Scince

Country

Iran (Islamic Republic of)

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+98 71 3228 8574

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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 autologus 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
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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