

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The Effect of Autologous Serum Therapy on Chronic Spontaneous Urticaria; Clinical Symptoms and Immunologic Changes

Protocol summary

Study aim

The effect of autologous serum therapy on Chronic Spontaneous Urticaria and immunological changes

Design

This study was an interventional clinical trial performed on 60 patients with chronic spontaneous urticaria. The sampling method was a non randomized and purpose-oriented method. After taking the history and performing the physical exam patients with symptoms lasting more than 6 weeks, a negative Prick test for oral and inhalatory allergens, aged higher than 15 years with normal laboratory result for CBC/diff, S/E, U/A, LFT, HBsAg, BUN, Cr, ESR, CRP, CH50, ANA, IgE and anti-Helicobacter pylori tests entered the study. Then the thyroid function test and the level of anti-thyroid antibodies (TSH, T4, T3, anti thyroperoxidase, anti thyroglobulin) were measured and autologous serum skin test (ASST) was performed. Based on the results of these tests patients were divided into two groups of 30 patients each. The first group (CAU group) included ASST positive patients with either normal or abnormal antibodies and thyroid function tests, and the second group (CIU group) included ASST negative patients with both normal antibodies and thyroid function tests

Settings and conduct

This study was in department of allergy and clinical immunology of Ghaem Hospital, Mashhad, Iran, in cooperation with the Inflammatory Research Center, Mashhad University of Medical Sciences. Patients voluntarily completed the consent form approved by the Ethics Committee of Mashhad University of Medical Sciences (920667) with knowledge of the goals and the methodology of this study

Participants/Inclusion and exclusion criteria

Entry requirements: Urticaria longer than 2 months, Aged higher than 15 years, Patients voluntarily completed the consent form, Negative Prick test for oral and inhalatory allergens, Normal result in anti-Helicobacter pylori tests, CBC, S / E, U / A, LFT, ESR, ANA

Exclusion criteria : Pregnancy, Physical urticarial, Cortisone and immunosuppressive use over the past 6 weeks, Use of medicines other than antihistamines, Other systemic diseases

Intervention groups

The use of autologous serum therapy has been suggested as an effective method to treat Chronic spontaneous urticaria. This study was to evaluate the effect of autologous serum therapy in treatment of Chronic spontaneous urticaria and the immunological changes caused by this treatment method. Treatment with autologous serum therapy was performed weekly for 10 weeks

Main outcome variables

Sample loss, the risk of infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180113038328N1**

Registration date: **2018-02-17, 1396/11/28**

Registration timing: **retrospective**

Last update: **2018-02-17, 1396/11/28**

Update count: **0**

Registration date

2018-02-17, 1396/11/28

Registrant information

Name

majid jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2770

Email address

jafari.md.ped@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2014-09-23, 1393/07/01

Expected recruitment end date
2015-03-06, 1393/12/15

Actual recruitment start date
2014-09-23, 1393/07/01

Actual recruitment end date
2015-04-19, 1394/01/30

Trial completion date
empty

Scientific title
The Effect of Autologous Serum Therapy on Chronic Spontaneous Urticaria; Clinical Symptoms and Immunologic Changes

Public title
The effect of Autologous Serum Therapy in Chronic Spontaneous Urticaria

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Symptoms lasting more than 6 weeks Negative Prick test for oral and inhalatory allergens Aged higher than 15 years Normal laboratory result for CBC/diff - S/E - U/A- LFT-HBsAg-BUN-Cr-ESR-CRP-CH50-ANA-IgE and anti-Helicobacter pylori tests

Exclusion criteria:

Physical urticaria Allergic and drug urticaria Vasculitis urticaria Cortisone and immunosuppressive use over the past 6 weeks (other than antihistamines) Pregnancy Lactation Other systemic diseases.

Age
From 15 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60
Actual sample size reached: 60

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Not 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

Knowledge and Health city, In the end of shahid Fakouri Blvd.mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

99191-91778

Approval date

2013-09-11, 1392/06/20

Ethics committee reference number

920667

Health conditions studied

1

Description of health condition studied

Chronic spontaneous urticaria

ICD-10 code

L50.8

ICD-10 code description

Other urticaria

Primary outcomes

1

Description

Spontaneous chronic urticaria is a qualitative variable with clinical parameters and cytokines is a of quantity Variable that is measured with PCR

Timepoint

Before and after treatment, as well as 4 weeks after the completion of treatment.

Method of measurement

Urticaria total severity score (TSS) ,dermatology quality of life index (DLQI),Real-time-PCR

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Treatment with autologous serum

therapy in chronic autoimmune urticaria(group 1) was performed weekly for 10 weeks. At each visit, 5 cc of venous blood was taken in sterile size 10 Falcon tubes, without EDTA anticoagulant. Blood samples were then kept at room temperature for 30 minutes to complete the blood coagulation. The serum was then isolated by centrifuging at 2000 rpm for 10 minutes. Immediately after the conclusion of isolation deep intramuscular injection of 2 cc of the centrifuged serum was performed in sterile conditions in buttock or arm area. To evaluate the effect of autologous serum therapy on clinical improvement of patients, urticaria total severity score and dermatology quality of life index questionnaire were used before treatment (week 0), at the end of treatment (week 10) and one month after treatment (week 14). Before starting and immediately after the completion of autologous serum therapy (weeks 0 and 10), 5 cc of venous blood from 20 randomly selected patients in chronic autoimmune urticaria(group1) was extracted for immunological examination. Then the expression of IL-17, IL-10, IL-4, FOXP3 and INF- γ genes was evaluated by Real -time PCR. Intervention group2: Treatment with autologous serum therapy in chronic idiopathic urticaria(group 2) was performed weekly for 10 weeks. At each visit, 5 cc of venous blood was taken in sterile size 10 Falcon tubes, without EDTA anticoagulant. Blood samples were then kept at room temperature for 30 minutes to complete the blood coagulation. The serum was then isolated by centrifuging at 2000 rpm for 10 minutes. Immediately after the conclusion of isolation deep intramuscular injection of 2 cc of the centrifuged serum was performed in sterile conditions in buttock or arm area. To evaluate the effect of autologous serum therapy on clinical improvement of patients, urticaria total severity score and dermatology quality of life index questionnaire were used before treatment (week 0), at the end of treatment (week 10) and one month after treatment (week 14). Before starting and immediately after the completion of autologous serum therapy (weeks 0 and 10), 5 cc of venous blood from 20 randomly selected patients in chronic idiopathic urticaria(group2) was extracted for immunological examination. Then the expression of IL-17, IL-10, IL-4, FOXP3 and INF- γ genes was evaluated by Real -time PCR.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of allergy and clinical immunology of Ghaem Hospital, Mashhad, Iran

Full name of responsible person

Majid jafari

Street address

Ahmadabad Blvd, Ghaem Hospital, mashhad Town

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Email

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Web page address

<http://arc.mums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology

Street address

Knowledge and Health city, In the end of shahid Fakouri Blvd. mashhad

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Web page address

<http://vcresearch.mums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Majid jafari

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Web page address<http://arc.mums.ac.ir>**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Majid jafari

Position

Consultant

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Web page address<http://arc.mums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Majid jafari

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Web page address<http://arc.mums.ac.ir>**Person responsible for updating data****Contact****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

Total non-identifiable data, the potential of the people sharing

When the data will become available and for how long

Immediately after the publication of results

To whom data/document is available

For all researchers

Under which criteria data/document could be used

Therapeutic and research use

From where data/document is obtainable

Majid jafari By email jafari.md.ped@gmail.com

What processes are involved for a request to access data/document

Immediately after the email

Comments

I have no comment