Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 theraphy 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

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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, FOXP3and 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, FOXP3and 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

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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

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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
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Person responsible for scientific inquiries

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Person responsible for updating data

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Other areas of specialty/work
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http://arc.mums.ac.ir

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