Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical Trial on efficacy of autologous plasma therapy on clinical symptoms of Patients with Chronic Spontaneous Urticaria Compared with no treatment

Protocol summary

Summary

The purpose of this study is to evaluate the efficacy of autologous plasma therapy on clinical symptoms of Chronic Spontaneous Urticaria. The design of this study is clinical trial, before and after, on patients suffering from two forms of idiopathic and autoimmune of chronic spontaneous urticaria. Major inclusion criteria are urticaria for more than 2 months; Age over than 15 year old; Consent to participate in the study; Negative Prick skin test for common inhalation and food allergens and normal findings in Lab data such as CBC (Complete Blood Count), ANA (Antinuclear antibody), ESR (Erythrocyte Sedimentation Rate), LFT (Liver Function Test), U/A (Urine Analysis) and S/E (Stool Exam). Major exclusion criteria are Pregnancy; Physical urticaria; Use of corticosteroid and immunosuppressive agents during the last 6 weeks; Use of drugs other than antihistamine and other systemic diseases. The patients will be gathered from Allergy Clinic in Bushehr Martyrs Hospital in Persian Gulf due to the history and clinical symptoms. Then they will be divided into idiopathic and autoimmune type of the disease after the autologous plasma skin test. After obtaining consent from participants in the study, patients will be treated with autologous plasma for 10 weeks. For evaluating the clinical improvement, the patients will be examined for the disease severity and activity before the treatment, every week during the treatment and one week after the treatment with DLQI (Dermatology Life Quality Index) and TSS (Total Symptoms Score) index. After the treatment evaluating the clinical improvement will be due to DLQI and TSS changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016040627260N1**

Registration date: **2016-05-10, 1395/02/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-10, 1395/02/21

Registrant information

Name

Afshin Shirkani

Name of organization / entity

Faculty of Medicine. Bushehr University of Medical Sciences.

Country

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences, Student Research Committee

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial on efficacy of autologous plasma therapy on clinical symptoms of Patients with Chronic Spontaneous Urticaria Compared with no treatment

Public title
Efficacy of autologous plasma therapy on clinical symptoms of Chronic Spontaneous Urticaria
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria are urticaria for more than 2 months; Age over than 15 year old; Consent to participate in the study; Negative Prick skin test for common inhalation and food allergens and normal findings in Lab data such as CBC (Complete Blood Count), ANA (Antinuclear antibody), ESR (Erythrocyte Sedimentation Rate), LFT (Liver Function Test), U/A (Urine Analysis) and S/E (Stool Exam). Exclusion criteria are Pregnancy; Physical urticaria; Use of corticosteroid and immunosuppressive agents during the last 6 weeks; Use of drugs other than antihistamine and other systemic diseases.
Age
From **15 years** old to **90 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Bushehr University of Medical Sciences
Street address
Salman Farsi Street, Bahmani, Medical Sciences Campus, First Floor, Bushehr, Iran
City
Bushehr
Postal code
Approval date
2016-02-20, 1394/12/01
Ethics committee reference number
ir.bpums.rec.1394.104

Health conditions studied

1

Description of health condition studied
Chronic Spontaneous Urticaria
ICD-10 code
L50.8
ICD-10 code description
Other urticaria (Urticaria: chronic, recurrent periodic)

Primary outcomes

1

Description
Qualitative clinical symptoms of urticaria
Timepoint
Before the treatment, every week during the treatment and one week after the treatment
Method of measurement
Changes in DLQI (Dermatology Life Quality Index)

Secondary outcomes

1

Description
Quantitative clinical symptoms of urticaria
Timepoint
Before the treatment, every week during the treatment for 10 weeks and one week after the treatment
Method of measurement
Changes in TSS (Total Symptoms Score) index

Intervention groups

1

Description
Patients will be divided into idiopathic and autoimmune forms of urticaria after the autologous plasma skin test. After consent to participate in the study, 5cc of brachial vein blood will be sampled first. Then we perform intradermal injection of equal measure from 0.1 cc of patient's centrifuged serum, histamine as a positive control and 0.9 % saline as a negative control at a distance of 3-5 cm from each other in the forearm and in the area that is free of rash in the past 48 hours with insulin syringes. Autologous plasma skin test is considered positive when after 30 minutes the swelling and redness diameter of serum injection area is equal or more than 1.5 mm greater than the swelling and redness of negative control injection site (normal saline). In order to treat with autologous plasma, we will take 5 ml of blood from the brachial vein using heparinized 10 ml sterile Falcon tubes from the subjects in Allergy Clinic in

Bushehr Martyrs Hospital in Persian Gulf in every week for 10 weeks. Patients' plasma will be separated by centrifugation at 1000 rpm for 10 minutes and 2 cc of it will be injected deep intramuscular in gluteal or arms area alternatively.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Allergy Clinic in Bushehr Martyrs Hospital in Persian Gulf

Full name of responsible person

Afshin Shirkani

Street address

Beginning Taleghani Ave. Azadi Square. Bushehr Martyrs Hospital in Persian Gulf. Bushehr. Iran.

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research of Bushehr University of Medical Sciences

Full name of responsible person

Soodabeh Zendeh Boodi

Street address

Salman Farsi Street, Bahmani, Medical Sciences Campus, First Floor, Bushehr, Iran

City

Bushehr

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research of Bushehr 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

Faculty of Medicine. Bushehr University of Medical Sciences.

Full name of responsible person

Afshin Shirkani

Position

Fellow of asthma, allergies and immunodeficiency diseases

Other areas of specialty/work

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Full name of responsible person

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Position

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Other areas of specialty/work

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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