

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Serum Autologous Therapy in patients with Idiopathic Chronic Urticaria

Protocol summary

Study aim

Improving the quality of life for patients with chronic idiopathic urticaria

Design

A Randomized Clinical Trials non Blinded - Two arm study with Control group receiving standard treatment.

Settings and conduct

5 cc blood is taken from the brachial vein centrifuged at 2000 rpm and 0.1 cc of the serum is subcutaneously injected into the forearm. Positive control of histamine (0.1 mg / ml) and negative control of 0.1 cc of normal saline will be injected in the same area at a distance of 5 cm from each other. In the event of a rupture of rat (more than 1.5 mm in diameter than normal saline (30 minutes after the test), a positive autologous serum test is assumed. During the study, patients will be allowed to use oral short-acting antihistamines only if necessary and in case of obesity.

Participants/Inclusion and exclusion criteria

Inclusion : History of hives at least 6 weeks
Exclusion : Finding a specific cause (physical urticaria) Pregnancy
Lactation Don't use a safe contraceptive method
Severe systemic illness Taking anticoagulant drugs
Taking systemic corticosteroids during the last 6 weeks
Taking immuno suppressor drugs during the last 6 weeks

Intervention groups

Intervention group: After separating the patient's serum, 2.5 cc of the patient's serum will be injected deep into the muscle (arm or hips) with syringe number 22. Injections will be on a weekly basis for up to 9 weeks. The patient will be re-evaluated at weeks 12 and 16.
control group : Will be treated by oral antihistamines .As a placebo 3 cc normal saline will be injected deep muscle.

Main outcome variables

Quality of Life ; Hives severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171222037986N2**

Registration date: **2019-01-15, 1397/10/25**

Registration timing: **retrospective**

Last update: **2019-01-15, 1397/10/25**

Update count: **0**

Registration date

2019-01-15, 1397/10/25

Registrant information

Name

Rasol Nasiri Kalmarzi

Name of organization / entity

Kurdistan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3323 0524

Email address

rnasiri@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-09-22, 1393/06/31

Expected recruitment end date

2016-03-18, 1394/12/28

Actual recruitment start date

2014-12-01, 1393/09/10

Actual recruitment end date

2016-03-18, 1394/12/28

Trial completion date

2016-09-20, 1395/06/30

Scientific title

Effects of Serum Autologous Therapy in patients with Idiopathic Chronic Urticaria

Public title

Serum Autologous Therapy in Idiopathic Chronic Urticaria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

History of hives at least 6 weeks

Exclusion criteria:

Finding a specific cause (physical urticaria) Pregnancy Lactation Don't use a safe contraceptive method Severe systemic illness Taking anticoagulant drugs Taking systemic corticosteroids during the last 6 weeks Taking immuno suppressor drugs during the last 6 weeks

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random blocking Group A (intervention) Group B (control) BABA ABAB BAAB ABBA BBAA BABA ABBA BBAA AABB BABA BAAB ABAB BABA ABBA ABAB AABB

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of Medical Science

Street address

Kurdistan University of Medical Sciences Vice Chancellor in Research Affair, Pasdaran Ave., Sanandaj, Iran

City

Sanandaj

Province

Kurdistan

Postal code

1344666177_

Approval date

2014-12-01, 1393/09/10

Ethics committee reference number

با توجه به اینکه در سال 1393 کد اخلاق صادر نمیشد نامه تاییده به ایمیل مرکز ارسال میگردد.

Health conditions studied

1

Description of health condition studied

Idiopathic Chronic Urticaria

ICD-10 code

L50.9

ICD-10 code description

Urticaria, unspecified

Primary outcomes

1

Description

Quality of Life

Timepoint

Weekly to Week 9, Week 12 and Week 16

Method of measurement

SF-36 quality of life questionnaire

2

Description

hives severity

Timepoint

Weekly to Week 9, Week 12 and Week 16

Method of measurement

Urticaria Activity score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with chronic idiopathic urticaria - 5 cc blood is taken from the brachial vein and centrifuged at 2000 rpm 2.5 cc of the patient's serum will be injected deep into the muscle (arm or hips) with needle 22. Injections will be on a weekly basis for up to 9 weeks.

Category

Treatment - Other

2

Description

Control group: Patients with chronic idiopathic urticaria - It was treated with oral antihistamines and will also be

injected deep into muscle as placebo 3 cc normal saline.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Rasoul Nasiri Kalmarzi

Street address

Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

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Sanandaj

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Kurdistan

Postal code

6618634683

Phone

+98 87 3323 0524

Email

rasool_nsr@yahoo.com

2

Recruitment center

Name of recruitment center

Kurdistan Asthma and Allergy Clinic

Full name of responsible person

Rasoul Nasiri Kalmarzi

Street address

Kurdistan Asthma and Allergy Clinic, Razi building, Vakil intersection, Sanandaj, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Ebrahim Ghaderi

Street address

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rasool_nsr@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Rasol Nasiri Kalmarzi

Position

Cellular & Molecular Research Center, Kurdistan University of Medical Sciences, Sanandaj, Iran

Latest degree

Subspecialist

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Rasol Nasiri Kalmarzi

Position

Cellular & Molecular Research Center, Kurdistan
University of Medical Sciences, Sanandaj, Iran

Latest degree

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Other areas of specialty/work

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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

All data is from the proposal, raw data and project reports

When the data will become available and for how long

Data is available from the legal system six months after publication for two years

To whom data/document is available

All persons will be able to access the Kurdistan University of Medical Sciences's request to the Kurdistan University of Medical Sciences.

Under which criteria data/document could be used

For legal issues and the need to use data in future studies

From where data/document is obtainable

Rasool Nasiri Kalmarzi - Be'sat Hospital - Kurdistan
University of Medical Science

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

After submitting a request to the Kurdistan Research and Technology Dept. of Science and Technology, a call for submission is given.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Behzad Khalafi

Position

Research Assistant (Researcher Deputy Soldier)

Latest degree

Medical doctor

Other areas of specialty/work

Public Health

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