Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Autologous Serum Skin Test as a Diagnostic Aid in Chronic Idiopathic Urticaria

Protocol summary

Summary
Background: Chronic urticaria is defined as urticaria persisting daily for more than six weeks, a significant number of them had autoimmune basis where autologous serum skin test is widely used for detection of chronic autoimmune urticaria. Objectives: To estimate the frequency of autoimmune urticarial in Iraqi patients utilizing the autologous serum skin test and to evaluate its results with the variable clinical features of chronic idiopathic urticaria. Methods: In this prospective study, 54 patients with chronic idiopathic urticaria will be investigated with autologous serum skin test where its results were examined with the different clinical parameters of chronic autoimmune urticaria.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT2013030912758N1**
Registration date: **2013-03-25, 1392/01/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2013-03-25, 1392/01/05

Registrant information
Name
Amar Hameed
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source
Iraqi Board for Medical specializations

Expected recruitment start date
2009-11-01, 1388/08/10
Expected recruitment end date
2013-11-01, 1392/08/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Autologous Serum Skin Test as a Diagnostic Aid in Chronic Idiopathic Urticaria

Public title
Investigation for chronic Idiopathic Urticaria
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria: All patients with chronic idiopathic urticaria who have active urticaria at time of presentation and the current attack started at least six week before the test. Exclusion criteria: children younger than 15 years of age and pregnant women were excluded from the study
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Not randomized
Randomization description
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
Iraqi Board for Medical specializations
Street address
Medical Collection Office, P.O. Box 61080 Postal Code 12114, Baghdad, Iraq.
City
Baghdad
Postal code
12114
Approval date
2009-10-09, 1388/07/17
Ethics committee reference number
1976

Health conditions studied

1

Description of health condition studied
urticaria
ICD-10 code
L50.1
ICD-10 code description
Idiopathic urticaria

Primary outcomes

1

Description
wheal and flare
Timepoint
30 minutes after intradermal injection of 0.05 ml of the patient’s serum into patient’s forearm
Method of measurement
wheal and flare at the tested site of a diameter (measured by taking the mean of the largest two diameters) at least 1.5 millimeters more than the wheal and flare induced at the control site

Secondary outcomes

1

Description
wheal and flare
Timepoint
45 minutes after intradermal injection of the patient’s serum into patient’s forearm
Method of measurement
wheal and flare at the tested site of a diameter (measured by taking the mean of the largest two diameters) at least 1.5 millimeters more than the wheal and flare induced at the control site

Intervention groups

1

Description
The Autologous Serum Skin Test (ASST) was performed by drawing 2cubic centimeters of venous blood and stored in a plane tube(not heparinized) and allowed to clot at room temperature ,after that the serum is separated by centrifuging the blood in a centrifuge for 10 minutes at 2000 RPM (Revolution per Minute). 0.05 ml of the patient’s serum is injected intradermally on volar aspect of the patient’s forearm at site not affected by a wheal in the last 24 hours
Category
Diagnosis

2

Description
At the same time a control test is done by injecting the same volume of normal saline at least 5 centimeters away from the serum injection site
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Baghdad Teaching Hospital
Full name of responsible person
Dr.Ammar F.Hameed
Street address
Medical city 61106
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Iraqi Board for Medical specializations

Full name of responsible person

prof.Khalifa sharquie

Street address

Medical Collection Office, P.O. Box 61080

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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

Iraqi Board for Medical specializations

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

Head of Department of Dermatology and Venereology, College of Medicine, University of Baghdad, Medic

Full name of responsible person

Professor Hayder R. Al-Hamamy

Position

Professor

Other areas of specialty/work

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Person responsible for updating data

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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