Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Assessing the safety and efficacy of Tranexamic Acid and cetirizine versus Cetirizine alone in relieving the symptoms of Chronic Urticaria; a triple-blind Randomized Clinical Trial

Protocol summary

Study aim

Assess the efficacy of Tranexamic Acid and cetirizine versus cetirizine alone in treatment of Chronic Urticaria

Design

Phase 2-3 clinical trial of a triple-blinded, placebo-controlled study with simple random allocation by www.randomization.com on 80 patients

Settings and conduct

Eighty patients with chronic urticaria who will attend Allergy and Clinical Immunology clinics of Shiraz University of Medical Sciences will enter the study. Neither the patients nor the professors and analyzer will know about the contents of the capsule and the study will be triple-blinded. Only the Pharmacist will be informed of the ingredients of each capsule.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with spontaneous chronic urticaria in association with the following symptoms: urticarial eruptions and/or recurrent angioedema for at least 6 weeks and who are older than 12 years old. Exclusion criteria: urticaria associated with a specific systematic disease including cutaneous and systemic mastocytosis; urticarial vasculitis; autoinflammatory diseases associated with cryopyrin; bradykinin angioedema and isolated angioedema whose origin is not clearly attributable to spontaneous chronic urticaria; presence of a contraindication to Tranexamic Acid and to Cetirizine such as any history of thromboembolic events as pulmonary thromboembolism and deep vein thrombosis among others and coagulopathy; unwillingness of the patients or their legal guardians to participate in the study.

Intervention groups

intervention group: will receive Cetirizine tabs and capsules containing Tranexamic Acid, control group: will receive a Cetirizine tabs and capsules containing placebo

Main outcome variables

D-dimer level; chronic urticaria quality of life (CU-QoL questionnaire); severity of chronic urticaria (UAS7 questionnaire)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220205053947N1**
Registration date: **2022-03-17, 1400/12/26**
Registration timing: **prospective**

Last update: **2022-03-17, 1400/12/26**
Update count: **0**

Registration date

2022-03-17, 1400/12/26

Registrant information

Name

Aida askarisarvestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

askariaida@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the safety and efficacy of Tranexamic Acid and cetirizine versus Cetirizine alone in relieving the symptoms of Chronic Urticaria; a triple-blind Randomized Clinical Trial

Public title
Tranexamic acid in chronic urticaria
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 12 years old Patients with spontaneous chronic urticaria, according to the criteria of the European Academy of Allergology and Clinical Immunology (EAACI) in agreement with the European Dermatology Forum (EDF), and the World Allergy Organization (WAO), corresponding to an association of the following symptoms: urticarial eruptions and/or recurrent angioedema for at least 6 weeks
Exclusion criteria:
Urticaria associated with a specific systematic disease including cutaneous and systemic mastocytosis Urticarial vasculitis Autoinflammatory diseases associated with cryopyrin Bradykinin angioedema Isolated angioedema whose origin is not clearly attributable to spontaneous chronic urticaria Presence of a contraindication to Tranexamic Acid and to Cetirizine such as any history of thromboembolic events as pulmonary thromboembolism and deep vein thrombosis Coagulopathy. Unwillingness of the patients or their legal guardians to participate in the study
Age
From **12 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Random Allocation will be achieved by a computer system by the website www.randomization.com. the website randomly allocates the patients (introduced as numbers) to two groups as A and B. allocation concealment will be achieved using dark envelopes. The method will be simple randomization.
Blinding (investigator's opinion)
Triple blinded
Blinding description
After obtaining an informed consent form the patients or their legal guardians, the patients will be divided to groups A and B. one of the groups will receive Cetirizine tabs and Tranexamic Acid capsules, while the other group will receive a Cetirizine tabs and capsules containing placebo made by school of Pharmacy of Shiraz University of Medical Sciences (Cetirizine tabs will be bought by the patients as they are the mainstay of treatment is urticaria). Neither the patients nor the professors will know about the contents of the capsule and the study will be double-blinded. Only the Pharmacist will be informed of the ingredients of each capsule.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Department of Pediatrics, Namazee hospital, Namazee Sq., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7193613311
Approval date
2022-02-14, 1400/11/25
Ethics committee reference number
IR.SUMS.MED.REC.1400.571

Health conditions studied

1

Description of health condition studied
chronic urticaria
ICD-10 code
L50.8
ICD-10 code description
Other urticaria

Primary outcomes

1

Description
Chronic Urticaria Quality of Life
Timepoint
before intervention and 2 weeks after intervention
Method of measurement
CU-QoL questionnaire

2

Description
Severity of Chronic Urticaria
Timepoint
before intervention and 2 weeks after intervention
Method of measurement
UAS7 questionnaire

3

Description
level of D-dimer
Timepoint
before intervention and 2 weeks after intervention
Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: will receive Cetirizine 10mg PO BiD for two weeks and Tranexamic Acid 500mg PO Q6h for two weeks
Category
Treatment - Drugs

2

Description
Control group: will receive Cetirizine 10mg PO BiD for two weeks and placebo capsule PO Q6h for two weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Allergy and clinical immunology clinic of Shiraz University of Medical Sciences; Imam Reza Clinic
Full name of responsible person
Aida Askarisarvestani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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Grant name
dissertation budget
Grant code / Reference number
23836
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Aida Askarisarvestani

Position
subspecialty fellow
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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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
The results of the study and the data will be available to other researchers who were not involved in this study for further studies upon reasonable request.
When the data will become available and for how long
the data will be available in 6 months.
To whom data/document is available
the data will be available to academic institutes upon reasonable request.
Under which criteria data/document could be used
the data will be available to academic institutes upon reasonable request.
From where data/document is obtainable
the data will be available via email.
What processes are involved for a request to access data/document
the request should be sent to askariaida@gmail.com and the reason should be explained.
Comments