

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

+98 917 112 9552

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

Street address

Allergy and Clinical Immunology Clinic, Imam Reza Clinic, Namazee Sq.

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3212 7000

Fax

+98 71 3647 4673

Email

askariaida@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mahtab Memarpour

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Province

Fars

Postal code

1433671348

Phone

+98 71 3212 2430

Email

memarpour@sums.ac.ir

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

Street address
Department of Pediatrics, Namazee hospital,
Namazee Sq., Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7193613311

Phone
+98 71 3647 4332

Email
askariaida@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Seyed Hesamedin Nabavizadeh

Position
professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Department of Pediatrics, Namazee hospital,
Namazee Sq., Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7193613311

Phone
+98 71 3647 4332

Email
drhesamnabavi@yahoo.com

Person responsible for updating data

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

Street address
Department of Pediatrics, Namazee hospital,
Namazee Sq., Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7193613311

Phone
+98 71 3647 4332

Email
askariaida@gmail.com

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