

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of naltrexone in treatment of chronic urticaria: double-blinded randomized clinical trial

Protocol summary

Study aim

Effect of Naltrexone in treatment of chronic urticaria

Design

A Clinical trial study with control group, parallel groups, double-blinded, randomized with block randomization on 62 patient

Settings and conduct

This study is performed on 62 patients in Hazrat Rasool Hospital. Patients are randomly divided into intervention group and control group. blinding will be performed on patients, Researcher and outcome assessor. Patients will assessed for severity of itching, urticaria and quality of life.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of chronic urticaria based on clinical criteria, lack of response to standard treatment, patients of both males and females, age over 12 years/
Exclusion criteria: pregnancy, breast feeding, allergy to naltrexone, substance abuse

Intervention groups

Intervention group: Tab Cetrizine 10mg, One every 6 hours (manufactured by Abidi Co., Iran) ; Tab Famotidin 40 mg, One every 12 hours (manufactured by Shafa Darou Co.Iran) and Tab Montellukast 10 mg, once daily (manufactured by Zahravi Co.Iran) as the main treatment that start from one week before the intervention, called wash out period. Then adding cap Nalteroxone 50 mg daily (manufactured by Alvahi Co.Iran) for 6 weeks./ Control group: baseline treatment and placebo Once daily

Main outcome variables

Primary outcome: Improve itching and urticaria based on (Weekly Urticaria Activity Score) UAS7 and (Visual Analogue Scale) VAS. Other outcome: Improve the quality of life based on (Dermatologic Life Quality Index)DLQI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210407050878N1**

Registration date: **2021-06-29, 1400/04/08**

Registration timing: **prospective**

Last update: **2021-06-29, 1400/04/08**

Update count: **0**

Registration date

2021-06-29, 1400/04/08

Registrant information

Name

Vahid Bakrani balani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3338 8955

Email address

bakranibalani.v@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-21, 1400/04/30

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of naltrexone in treatment of chronic urticaria:
double-blinded randomized clinical trial

Public title

Effect of naltrexone in chronic urticaria

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of chronic urticaria based on clinical criteria
Lack of response to standard treatment Patients of both
males and females Age over 12 years

Exclusion criteria:

Pregnancy Breast feeding Allergy to naltrexone
Substance abuse

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization is done using the
Sealedenvelope.com Site with block size of 4 and
considering a unique code for each participant. To hide
random allocation, the drug for each person is placed in
a package whose envelope is opaque and a unique code
is affixed to it.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, blinding is performed for the following
levels. Patient: Placebo is used which is similar to the
main drug in terms of color, shape, appearance and
smell. The received intervention is specified by the code
and the researcher is not aware of the codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Faculty of Medicine, Iran
University of Medical Sciences

Street address

Faculty of Medicine, Iran University of Medical
Sciences, Shahid Hemmat Highway, Next to Milad
Tower

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-05-10, 1400/02/20

Ethics committee reference number

IR.IUMS.FMD.REC.1400.115

Health conditions studied

1

Description of health condition studied

Urticaria

ICD-10 code

L50

ICD-10 code description

Urticaria

Primary outcomes

1

Description

Itching Score based on UAS7 (Urticaria Activity Score7)

Timepoint

Itching score based on UAS7 (Urticaria Activity Score7):
During the week before beginning intervention, during
the second week of intervention, during the fourth week
of intervention

Method of measurement

Based on UAS7 (Urticaria Activity Score7)

2

Description

Urticaria Score based on UAS7 (Urticaria Activity Score7)

Timepoint

Urticaria score based on UAS7 (Urticaria Activity Score7):
during the week before beginning intervention, during
the second week of intervention, during the fourth week
of intervention

Method of measurement

Based on UAS7 (Urticaria Activity Score7)

Secondary outcomes

1

Description

Itching score based on VAS (Visual Analogue Scale)

Timepoint

Before intervention, end of the second week of

intervention, end of the fourth week of intervention

Method of measurement

Based on VAS (Visual Analogue Scale)

2

Description

Quality of life based on DLQI (Dermatologic Life Quality Index)

Timepoint

Before intervention, end of the second week of intervention, end of the fourth week of intervention

Method of measurement

Based on DLQI (Dermatologic Life Quality Index)

Intervention groups

1

Description

Intervention group: Tab Cetrizine 10mg, One every 6 hours (manufactured by Abidi Co., Iran) ; Tab Famotidin 40 mg, One every 12 hours (manufactured by Shafa Darou Co.Iran) and Tab Montellukast 10 mg, once daily (manufactured by Zahravi Co.Iran) as the main treatment that start from one week before the intervention, called wash out period. Then adding cap Nalteredoxone 50 mg daily (manufactured by Alhavi Co.Iran) for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: Tab Cetrizine 10mg, One every 6 hours (manufactured by Abidi Co., Iran) ; Tab Famotidin 40 mg, One every 12 hours (manufactured by Shafa Darou Co.Iran) and Tab Montellukast 10 mg, once daily (manufactured by Zahravi Co.Iran) as the main treatment that start from one week before the intervention, called wash out period. Then adding cap Placeco 50 mg daily (manufactured by Alhavi Co.Iran) for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool Hospital

Full name of responsible person

Vahid Bakrani Balani

Street address

Hazrat Rasool Hospital, Niayesh St, Sattarkhan Ave.

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1445613131

Phone

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Email

bakranibalani.v@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyyed Abbas Motevalian

Street address

Deputy of research and technology, Iran University of Medical Sciences, Shahid Hemmat Highway, next to Milad Tower

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+98 21 8670 2503

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motevalian.a@iums.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Vahid Bakrani Balani

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Allergy and Clinical Immunology

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Hazrat Rasool Hospital, Niayesh St, Sattarkhan Ave.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mohammad Hasan Bemanian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Allergy and Clinical Immunology

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

Iran University of Medical Sciences

Full name of responsible person

Vahid Bakrani Balani

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Allergy and Clinical Immunology

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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 collected data can be shared after deidentifying participants

When the data will become available and for how long

Data will become available 6 months after publication

To whom data/document is available

Individual participant data only available for people working in academic institutions.

Under which criteria data/document could be used

-

From where data/document is obtainableDr. Bakrani Balani Vahid email address
bakranibalani.v@iums.ac.ir**What processes are involved for a request to access data/document**

The data will be sent on month after receiving the e-mail.

Comments