Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Alhavi 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
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Iran (Islamic Republic of)
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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 Nalteroxone 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Vahid Bakrani Balani
Position
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Latest degree
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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 obtainable
Dr. 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 recieving the e-mail.
Comments