Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparative study of the therapeutic effect of citrizine and fexofenadine in the control of medication-induced skin lesions in hospital intensive care unit

Protocol summary

Study aim
Comparative study of the efficacy of citrizine and foxfenadine in controlling drug-induced skin lesions in hospital intensive care unit to control skin lesions and improve patient quality of life and reduce mortality in hospital intensive care unit

Design
Clinical trial on sixty patients in two groups, community-based and pragmatic therapy, with parallel groups, single blind, randomized to two groups

Settings and conduct
Patients admitted to the intensive care unit will receive either oral or gavage Fexofenadine tablets 120 mg every 12 hours for a maximum of ten days and oral or gavage cetirizine tablets 10 mg every 12 hours.Then questionnaire information before and after It will be completed after receiving the drug.unilateral blinding is done so that the participant is blind and does not know the grouping and the number of participants in the study.

Participants/Inclusion and exclusion criteria
Obtain informed and patient consent in the ICU for at least 48 hours. No history of skin diseases.

Intervention groups
Fexofenadine 120 mg of one tablet every 12 hour for ten days in one group and cetrizin 10 mg of one tablet every 12 hour for two week in another group

Main outcome variables
Evaluation of drug-induced skin lesions; severity of drug-induced skin lesions and extent of drug-induced skin lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20080901001165N47**
Registration date: **2020-04-16, 1399/01/28**
Registration timing: **retrospective**

Last update: **2020-04-16, 1399/01/28**
Update count: **0**

Registration date
2020-04-16, 1399/01/28

Registrant information

Name
Yunes Panahi

Name of organization / entity
Baqiyatallah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 21 8821 1524

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-01, 1397/09/10

Expected recruitment end date
2019-11-06, 1398/08/15

Actual recruitment start date
2018-12-11, 1397/09/20

Actual recruitment end date
2020-02-09, 1398/11/20

Trial completion date
2020-02-19, 1398/11/30

Scientific title
Comparative study of the therapeutic effect of citrizine and fexofenadine in the control of medication-induced skin lesions in hospital intensive care unit

Public title
A comparative study of the therapeutic effect of cetirizine and fexofenadine on the control of skin lesions caused by drugs in the intensive care unit(ICU).
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients stay in ICU for at least 48 hours No history of skin diseases Be on medication, so that people in both groups receive their own treatment appropriate to their illness.
Exclusion criteria:
The patient is in the ICU for less than 48 hours. Find non-pharmacological skin diseases
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is conducted using random number table and considering a 1:1 ratio.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patient groups are divided into two groups and except the researcher, other people involved in the study do not know of the intervention or control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University / Pharmaceutical Sciences Branch
Street address
Yasaman alley, Yakhchal steet, Shariati street
City
Tehran
Province
Tehran
Postal code
1941933111
Approval date
2018-08-28, 1397/06/06
Ethics committee reference number
IR.IAU.PS.REC.1397.348

Health conditions studied

1

Description of health condition studied
Drug induced skin eruption
ICD-10 code
R21
ICD-10 code description
Rash and other nonspecific skin eruption

Primary outcomes

1

Description
Type of drug-induced skin lesion
Timepoint
Before intervention, 10 days after intervention
Method of measurement
Questionnaire

2

Description
The severity of the skin lesions
Timepoint
Before intervention, 10 days after intervention
Method of measurement
questionnaire

3

Description
The extent of skin lesions
Timepoint
Before intervention, 10 days after intervention
Method of measurement
questionnaire

Secondary outcomes

1

Description
Side effect of Faxofenadine
Timepoint
Before intervention, after ten days
Method of measurement
Questionnaire

2

Description

Side effect of cetirizine
Timepoint
Before intervention, after ten days
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: Fexofenadine tablets 120 mg every 12 hours for 10 days
Category
Treatment - Drugs

2

Description
Intervention group: Cetirizine 10 mg tablet every 12 hours for 10 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatallah Specialty Hospital
Full name of responsible person
Yunes panahi
Street address
Wank-Sheikh Baha'i South street -Baqiyatallah Faculty of Pharmacy
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Farshad Hashemian
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Islamic Azad University of Pharmaceutical Sciences, Yakhchal St., Shariati St., Tehran, Iran
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Hashemian.f@iaups.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University
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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Yunes panahi
Position
pharmacotherapy professor
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The clinical report will be published in paper form
When the data will become available and for how long
Start access period after printing results
To whom data/document is available
Researchers in the field of health
Under which criteria data/document could be used
If the documentation is protected
From where data/document is obtainable
yunes panahi
What processes are involved for a request to access data/document
Send project email
Comments