Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The comparison of the effect of N - acetylcysteine and angiotensin-converting enzyme inhibitors with angiotensin-converting enzyme inhibitors alone to control blood pressure in hypertensive patients referred to Hajar medical hospital

Protocol summary

Summary

This study is to carry out to compare the effect of N - acetylcysteine and angiotensin- converting enzyme inhibitors with angiotensin-converting enzyme inhibitors alone to control blood pressure in hypertensive patients which aim to refer to Hajar hospital. In this study, 126 patients with systolic hypertension higher than 140mmHg are to be selected accessibly and to be randomly divided into two groups. The first group is to be prescribed NAC tablet with the doses of 600 mg dissolved in 30 cc water / 12 hours through taking along with ACEI for 2 months and the second group is to be treated with ACEI alone. Blood pressures of all patients is to be checked each 5-7 days. After that, for two weeks, none of the groups is to be received NAC and only is to be received ACEI. During this period as well, the blood pressure of the patients is to be measured every 5-7 days in medical clinics and after two weeks, the program is to be switched. i.e... for two months, the group previously take ACEI and NAC, is to be taken ACEI alone and the group which previously take ACEI , is to be treated with NAC and ACEI. Similar to the former two - months period, their blood pressure are to be checked every 5-7 days. The inclusion criteria: having age of 18 years old or more; systolic blood pressure of 140 mmHg or higher despite of taking ACEI. The people who are afflicted with Cystinuria; has kidney stones especially Cysteine stones; show severe sensitivity to ACEI and NAC and also the patients who need the other antihypertensive drugs besides ACEI to control their blood pressure are to be excluded from the study.

General information

Acronym

The effect of N - acetylcysteine and angiotensin converting enzyme inhibitors

IRCT registration information

IRCT registration number: **IRCT2014022616750N1**
Registration date: **2014-04-21, 1393/02/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-04-21, 1393/02/01

Registrant information

Name

Mahmoud Mobasheri

Name of organization / entity

Shahrekord university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of research and technology , Shahrekord university of medical sciences , Shahrekord, Iran

Expected recruitment start date

2014-03-02, 1392/12/11

Expected recruitment end date

2014-04-22, 1393/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The comparison of the effect of N - acetylcysteine and angiotensin- converting enzyme inhibitors with angiotensin-converting enzyme inhibitors alone to control blood pressure in hypertensive patients referred to Hajar medical hospital

Public title
The comparison of the effect of N-acetylcysteine and angiotensin- converting enzyme inhibitors with angiotensin-converting enzyme inhibitors alone to control blood pressure in hypertensive patients

Purpose
Treatment

Inclusion/Exclusion criteria
The inclusion criteria: having age of 18 years old or more; systolic blood pressure of 140 mmHg or higher despite of taking ACEI. The people who are afflicted with Cystinuria; has kidney stones especially Cysteine stones; show severe sensitivity to ACEI and NAC and also the patients who need the other antihypertensive drugs besides ACEI to control their blood pressure are to be excluded from the study.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **126**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahrekord, Medical Sciences University Of

Street address
Deputy of research and technology, central office of university of medical sciences, Kashani boulevard, Shahrekord

City
Shahrekord

Postal code

Approval date
2010-05-15, 1389/02/25

Ethics committee reference number
1-2-89

Health conditions studied

1

Description of health condition studied
Blood pressure

ICD-10 code
I10.0

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Blood pressure

Timepoint
Before the study, every 5-7 days during the study for two months

Method of measurement
Measured based on mmHg by Mercury barometer

Secondary outcomes

empty

Intervention groups

1

Description
The first group is to be prescribed NAC with the doses of the 600mg dissolved in 30cc water/12hrs along with ACEI for two months. The second group is to be treated with ACEI alone. During this two months , blood pressure of both groups is to be measured every 5-7 day. After that, none of each group will received NAC and only is to be taken ACEI.In this period also, the blood pressure is to be measured every 5-7 day. After two weeks, their program is to be switched.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hajar hospital

Full name of responsible person
Dr.Arsalan Khaledi Far

Street address
Parastar street, Hajar hospital, Heart group
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of research and technology, Shahrekord university of medical sciences
Full name of responsible person
Dr.Mahmoud Mobasheri
Street address
Kashani Boulevard, central office of university of medical sciences, deputy of research and technology
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of research and technology, Shahrekord university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahrekord,Medical Sciences University Of
Full name of responsible person
Dr.Mahmoud Mobasheri
Position
Associate professor of epidmiology group
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty