

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of cardiology

Full name of responsible person

Dr.Arsalan khaledi Far

Position

Cardiologist

Other areas of specialty/work**Street address**

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Hajar hospital

Full name of responsible person

Dr. Arsalan Khaledifar

Position

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Web page address**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