Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The effect of adjustment Additive Salt with a medical salt shaker on Blood Pressure and 24-Hour Urine Sodium in pre-hypertensive persons

Protocol summary

Study aim
Determining the effect of adjusting salt addition using a medical salt shaker on blood pressure and 24-hour urine sodium in prehypertension

Design
Clinical trial with control and intervention groups, double-blind, randomized, on 70 patients

Settings and conduct
A clinical trial with a double-blind and randomized control group on 70 people from Rahnan, Khadijah Kobri and Amirhamzeh health centers.

Participants/Inclusion and exclusion criteria
entry criteria 1- Reading and writing literacy . 2- Living in Isfahan (being available) 3- People who are 20-65 years old. and have the ability to perform their daily activities alone. 4- The participants should be of both sexes (non-pregnant women). 5- Having a systolic blood pressure of 120-139 and a diastolic blood pressure of 80-89. Non-entry criteria Having even one occasion of systolic blood pressure above 14 in previous visits to the doctor

Intervention groups
In this study, a medical salt shaker was provided to the intervention group, how to use it and they were also taught how to follow a low salt diet along with it, and in three stages before the start of the intervention. Two weeks and one month after the intervention, blood pressure and 24-hour urine sodium laboratory index were measured in two stages before and after the intervention in two intervention groups.The only difference between the control group and the intervention group is not having a medical salt shaker.

Main outcome variables
Independent variable: medical salt tank, Dependent variable: 24-hour urine sodium laboratory index and blood pressure changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220815055699N1**
Registration date: **2023-06-29, 1402/04/08**
Registration timing: **retrospective**

Last update: **2023-06-29, 1402/04/08**
Update count: **0**

Registration date
2023-06-29, 1402/04/08

Registrant information
Name
Zahra Shokrani
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
2016-10-22, 1395/08/01

Expected recruitment end date
2016-11-20, 1395/08/30

Actual recruitment start date
2016-10-22, 1395/08/01

Actual recruitment end date
2016-11-20, 1395/08/30

Trial completion date
2017-01-20, 1395/11/01

Scientific title
The effect of adjustment Additive Salt with a medical salt shaker on Blood Pressure and 24-Hour Urine Sodium in pre-hypertensive persons

Public title
Effect of medical salt shaker on blood pressure and urinary sodium
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
1- Reading and writing literacy . 2- Not having a speech disorder or hearing disorder . 3- Living in Isfahan (being available). 4- People who are 20-65 years old. and have the ability to perform their daily activities alone. 5- People who have not used other educational methods and complementary medicine such as massage therapy in the previous three months to control their blood pressure. 6- The participants should be of both sexes (non-pregnant women). 7- The patients should be interested in participating in the study. 8- According to the patient, a history of severe mental stress in six months do not have a past (such as death of relatives and separation from spouse) and are not under severe stress at the time of conducting the research. 9- Having a systolic blood pressure of 120-139 and a diastolic blood pressure of 80-89. 10- Do not participate in another blood pressure control program. 11- People who, according to their health record, have mental retardation, blindness, deafness, or an active mental illness (schizophrenia) , bipolar disorder and depression) are not severe. 12- People who are not addicted to narcotics, painkillers and psychotropic drugs. 13- People who do not have chronic pain syndromes.
Exclusion criteria:
Not having enough motivation to cooperate in the plan and comply with the things taught. People who had a systolic blood pressure of 14 or higher even once in previous visits to the doctor. Cases of excessive fluid accumulation in the body such as cirrhosis, etc., use of diuretic drugs, active bleeding or severe sweating.
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
By the researcher's colleague, the words intervention and control were written on cards with the same number of samples and put in a bag, and each of the research units randomly took out one of the cards from the bag and thus was placed in the intervention or test group. they got. After the samples with the characteristics of the research units were selected, both groups participated in the training session related to proper diet and the proper diet training pamphlets were given to both groups. And the intervention group participated in the adjustment program of added salt using the daily salt measurement tool. It should be noted that the training session was held by the researcher.
Blinding (investigator's opinion)
Double blinded
Blinding description
The researcher's colleague put the samples into two intervention and control groups, and the samples and the researcher did not know about this issue
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of isfahan University of Medical Sciences
Street address
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services
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Postal code
81746-73461
Approval date
2016-10-22, 1395/08/01
Ethics committee reference number
ir.mui.rec.1395.3.600

2

Ethics committee
Name of ethics committee
Ethics committee of isfahan University of Medical Sciences
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Postal code
81746-73461
Approval date
2016-10-22, 1395/08/01
Ethics committee reference number
ir.mui.rec.1395.3.60

Health conditions studied

1

Description of health condition studied
Prehypertension
ICD-10 code
I10-I15
ICD-10 code description
Hypertensive diseases

Primary outcomes

1

Description
Blood pressure and 24-hour urine sodium
Timepoint
Before the start of the intervention Two weeks and one month after the start of the intervention
Method of measurement
Mercury sphygmomanometer and 24-hour urine test

Secondary outcomes

empty

Intervention groups

1

Description
For the intervention group, an educational session was held with the content of explaining the nature of hypertension disease, symptoms of the disease, classification, cause of occurrence and modifiable and non-modifiable risk factors, etc., the importance of how to use a proper diet and the components of the food pyramid, the DASH food pattern, the amount salt, fruits and vegetables, and at the end of the meeting, their questions were answered, and pamphlets containing the training materials, 24-hour urine collection containers, and a medical salt box were provided to each person in the intervention group by the researcher's colleague. The people of the intervention group were emphasized to use only medical salt shakers to add salt to their food.Before the intervention and two weeks and one month after the intervention, their blood pressure was measured, and before and after the intervention, the 24-hour urine sodium of the subjects was measured
Category
Lifestyle

2

Description
Control group: For the control group, like the intervention group, an educational session was held, with the content of explaining the nature of hypertension, symptoms, classification, cause of occurrence, modifiable and non-modifiable risk factors, etc., the importance of how to use a proper diet and the components of the pyramid. food, the DASH food pattern, the amount of salt consumed and fruit and vegetables, and at the end of the meeting, their questions were answered, and pamphlets containing the taught materials and 24-hour urine collection containers were delivered. And before the start of the intervention, two weeks and one month After the intervention, their blood pressure was measured, and before and after the intervention, the 24-hour urine sodium of the subjects was measured.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Khadijah Kobri Clinic, Rahnan Clinic and Amir Hamzeh Clinic
Full name of responsible person
Zahra shokrani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Vice President of Research and Technology
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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

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Zahra shokrani

Position
Icu headnurse

Latest degree
Master

Other areas of specialty/work
Nursery

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Contact

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Person responsible for updating data

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Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Demographic information, blood pressure and urinalysis results can be shared

When the data will become available and for how long
Access starts one month after results are published

To whom data/document is available
Researchers working in academic and scientific institutions and students

Under which criteria data/document could be used
There are no special conditions

From where data/document is obtainable
Shokrani@gmail.com

What processes are involved for a request to access

data/document	Within one month from the time of application
Comments	