Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effects of a reduced-sodium, high-potassium salt substitute on hypertensive and normal population of Baharlou Clinic clients, Tehran, Iran at 2016-2017

Protocol summary

Summary

The purpose of this intervention is to investigate the consequences of a "low sodium, high potassium" salt on a group of Iranian hypertensive patients and general population. Intervention Group would be 50 hypertensive patients with their family enrolled to receive the low sodium salt (80 percent sodium chloride and 20 percent potassium chloride) for 3 months and Control Group would be 50 hypertensive patients with their family enrolled to receive regular salt (100 percent sodium chloride) for 3 months. Sample size is 125 in each group (50 hypertensive + 75 individuals with normal blood pressure) which sums up to 250 individuals. The method is double blind randomized clinical trial. Outcome measures include blood pressure, sodium & potassium in 24 h urine, attrition rate due to unacceptable taste of the salt.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016103130572N1**
Registration date: **2016-12-08, 1395/09/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-08, 1395/09/18

Registrant information

Name

Mohammad Mohammadi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

- Research Deputy of Tehran University of Medical Sciences - Shournamak Yazd Company

Expected recruitment start date

2016-12-04, 1395/09/14

Expected recruitment end date

2017-03-17, 1395/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of a reduced-sodium, high-potassium salt substitute on hypertensive and normal population of Baharlou Clinic clients, Tehran, Iran at 2016-2017

Public title

The effects of a salt substitute on an Iranian population.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Age 25-65; Blood Pressure equal to or greater than 140 Systolic or 90 Diastolic in three measurements in two settings or consuming an anti-hypertensive drug; Cooperative with consuming salt for 3 months Exclusion Criteria: Abnormal Serum Creatinine; Abnormal Serum Urea; Consuming medications: Digoxin, Lithium, K-Sparing Diuretics; Acute or Severe

Cardiovascular Disease; Psychotic Disorders; Eating fast-foods or take-away foods or going to restaurant more than once a week

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **250**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics commitee of Medicine Faculty, Tehran University of Medical Sciences

Street address
Building Number 1, Medicine Faculty, TUMS, Poursina St., Keshavarz Boulevard

City
Tehran

Postal code

Approval date
2016-11-26, 1395/09/06

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1395.1118

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Systolic Blood Pressure

Timepoint
First Day, End of Month1, End of Month2, End of Month3

Method of measurement
digital blood pressure monitor (3 measurements in each visit)

2

Description
Diastolic Blood Pressure

Timepoint
First Day, End of Month1, End of Month2, End of Month3

Method of measurement
digital blood pressure monitor (3 measurements in each visit)

3

Description
Sodium in 24 hour Urine collected

Timepoint
At first day and last day of the study

Method of measurement
24-h urine collection

4

Description
Potassium in 24 hour urine collection

Timepoint
At first day and last day of the study

Method of measurement
24-h urine collection

Secondary outcomes

1

Description
Attrition rate due to unacceptable salt taste

Timepoint
End of the study

Method of measurement
Attrition rate due to unacceptable salt taste in intervention group compared to control group

Intervention groups

1

Description
Intervention Group: Low sodium salt (80 percent sodium Chloride and 20 percent Potassium Chloride) for 3 months as the exclusive salt consumed

Category
Prevention

2

Description
Control Group: Regular Salt (100 percent sodium chloride) for 3 month as the exclusive salt consumed
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Preventive & Health Promoting Clinic, Baharlou Hospital
Full name of responsible person
Dr. Mohammad Mohammadi
Street address
Rah-Ahan Sq, Behdari St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Medicine Faculty, Tehran Universiy of Medical Sciences
Full name of responsible person
Ms. Khorrami
Street address
Building Number 1, Medicine Faculty, TUMS, Poursina Ave., Keshavarz Boulevard
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Medicine Faculty, Tehran Universiy of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Shournamak Yazd Company
Full name of responsible person
Mr. Honaryar
Street address
37 Fakhr Razi St., Enqelab Ave.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shournamak Yazd Company
Proportion provided by this source
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
Community Medicine Department, TUMS
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Person responsible for scientific inquiries

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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