

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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

+98 21 8896 2357

###### Email address

mohammadi.mo@razi.tums.ac.ir

##### 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 committee 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 University 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 University 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

##### Full name of responsible person

Mohammad Mohammadi

##### Position

MD

##### Other areas of specialty/work

##### Street address

Community Medicine Department, Building number 4, TUMS, Poursina St., Kesharz Boulevard

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Community Medicine Department

##### Full name of responsible person

Alipasha Meysamie

##### Position

Full Professor of Community & Preventive Medicine

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Community Medicine, Tehran University of Medical Sciences  
**Full name of responsible person**  
Mohammad Mohammadi  
**Position**  
Resident of Community Medicine  
**Other areas of specialty/work**  
**Street address**  
Community Medicine, Building Number 4, Medicine Faculty, Poursina St., Keshavarz Boulevard  
**City**

## 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*