

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of oral zinc sulfate supplementation on improving taste and dry mouth in patients undergoing chronic hemodialysis

Protocol summary

Registration timing: **prospective**

Study aim

Evaluation of the effect of zinc sulfate on dry mouth improvement in dialysis patients Determination of the effect of zinc sulfate consumption on improving taste sensation in dialysis patients Determination of the relationship between zinc blood level and dysgeusia Determination of the relationship between blood level of zinc and dry mouth

Last update: **2022-08-20, 1401/05/29**

Update count: **0**

Registration date

2022-08-20, 1401/05/29

Registrant information

Name

Sakine Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3823 7822

Email address

sakinehashemi@yahoo.com

Design

Clinical efficiency with control group, which patients are divided into two groups of 25 persons as unelected. This study was designed as randomize controlled efficiency.

Settings and conduct

Patients will be selected from dialysis ward of Namazi Hospital in Shiraz where participants are blinded and the study is one-sided.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: no active infection, no active cancer, no active heart disease, age group of 18-70 years and minimum onset of dialysis for 6 months.

Intervention groups

The population in this study consisted of dialysis patients referred to Namazi Hospital, out of 100 hemodialysis patients who are dialysis in Namazi Hospital, 50 patients will be voluntarily divided into two groups of 25 patients, the duration of the study is 8 weeks, and one group receives zinc supplement with a dose of 100 mg daily and the other group receives placebo. receives

Main outcome variables

Improving taste sense and dry tongue in patients undergoing chronic hemodialysis

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral zinc sulfate supplementation on improving taste and dry mouth in patients undergoing chronic hemodialysis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220808055636N1**

Registration date: **2022-08-20, 1401/05/29**

Public title

The effect of zinc sulfate on taste and dry mouth in dialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No active infection No active cancer No active heart disease Age group of 18-70 years Minimum onset of dialysis is 6 months.

Exclusion criteria:

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to perform Concealment, the table of the control group, as well as the drug cans, one including placebo and the other including zinc sulfate, will be provided to a person except the interviewer and evaluator, and the mentioned number will be placed on the cans and the evaluator will be unaware of which number belongs to each grocer.

Placebo

Used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

No23,Abolfathi Blvd, Fallahi Ave, Pasdaran Blvd, Shiraz Town

City

Shiraz

Province

Fars

Postal code

7185734871

Approval date

2022-08-12, 1401/05/21

Ethics committee reference number

IR.SUMS.MED.REC.1401.178

Health conditions studied

1

Description of health condition studied

Evaluation of dysgeusia and dry tongue in patients undergoing chronic hemodialysis

ICD-10 code

XVIII

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes

1

Description

Percentage of patients with dysgeusia and dry mouth in chronic hemodialysis patients

Timepoint

Evaluate dry mouth and dysgeusia at the beginning of the study and 8 weeks after taking zinc sulfate tablets

Method of measurement

Dry mouth and dysgeusia questionnaire

Secondary outcomes

1

Description

Increased blood zinc levels in patients

Timepoint

Measurement of zinc blood level at the beginning of the study and 8 weeks after the beginning of the study

Method of measurement

Measurement of zinc blood level by blood test

Intervention groups

1

Description

Intervention group: The society of Amari in this study is dialysis patients referred to Namazi hospital that out of 100 hemodialysis patients who are dialysis in Namazi Hospital, 50 patients voluntarily and in case of no concurrent disease, participate in the present study. Patients are divided into two groups of 25 people, one group receives zinc supplement at a dose of 100 mg daily and the other group receives placebo .At the beginning of the study, dysgeusia and dry mouth questionnaires are filled by patients' and scoring is done and a blood sample is taken to determine serum zinc levels. . At the end of the study, the dysgeusia and dry

mouth questionnaire will be filled again and the status change will be evaluated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi hospital

Full name of responsible person

Sakine Hashemi

Street address

No23,Abolfathi Blvd, Fallahi Ave, Pasdaran Blvd,
Shiraz Town

City

Shiraz

Province

Fars

Postal code

7185734871

Phone

+98 71 3823 7822

Email

sakihashemi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mahtab Memarpour

Street address

No23,Abolfathi Blvd, Fallahi Ave, Pasdaran Blvd,
Shiraz Town

City

Shiraz

Province

Fars

Postal code

7185734871

Phone

+98 71 3823 7822

Email

sakihashemi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sakine Hashemi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

No23,Abolfathi Blvd, Fallahi Ave, Pasdaran Blvd,
Shiraz Town

City

Shiraz

Province

Fars

Postal code

7185734871

Phone

+98 71 3823 7822

Email

sakihashemi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sakine Hashemi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

No23,Abolfathi Blvd, Fallahi Ave, Pasdaran Blvd,
Shiraz Town

City

Shiraz

Province

Fars

Postal code

7185734871

Phone

+98 71 3823 7822

Email

sakihashemi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sakine Hashemi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

No23,Abolfathi Blvd, Fallahi Ave, Pasdaran Blvd,
Shiraz Town

City

Shiraz

Province

Fars

Postal code

7185734871

Phone

+98 71 3823 7822

Email

sakihashemi@yahoo.com

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Potential data can be shared after people are identified.

When the data will become available and for how long

One month after printing the results

To whom data/document is available

Academic and Scientific Institutions

Under which criteria data/document could be used

No special conditions requiredس

From where data/document is obtainable

sakihashemi@yahoo.com

What processes are involved for a request to access data/document

Request by e-mail

Comments