

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Effect of zinc sulfate on treatment of tinnitus and its related to lipid profile changes

#### Protocol summary

##### Study aim

Effect of zinc sulfate on serum lipid changes in patients with tinnitus

##### Design

all patients with tinnitus including organic and non organic (psychotic) will selected after clinical and microscopic examination and audiological tests and diagnosis cause of tinnitus

##### Settings and conduct

zinc sulfate capsule (220mg) will administrate daily for 30 days. Then, patients will clinically examine and rate of treatment will evaluate. blood sample will collect and zinc concentration and lipid level in serum will measure.

##### Participants/Inclusion and exclusion criteria

entrance criteria: all patients with tinnitus exit criteria:lack of patients compliance for study continue, 2-patient under 18 and over 80 yaers

##### Intervention groups

receiving zinc sulfate capsule

##### Main outcome variables

serum concentration of zinc and lipid

#### General information

##### Reason for update

##### Acronym

TZL

##### IRCT registration information

IRCT registration number: **IRCT20180624040213N1**

Registration date: **2018-09-16, 1397/06/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-16, 1397/06/25**

Update count: **0**

##### Registration date

2018-09-16, 1397/06/25

##### Registrant information

##### Name

Hossein Najafzadehvarzi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3247 6421

##### Email address

h.najafzadeh@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2019-01-21, 1397/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of zinc sulfate on treatment of tinnitus and its related to lipid profile changes

##### Public title

Effect of zinc sulfate on treatment of tinnitus and its related to lipid profile changes

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

all patients with chronic tinnitus with age 18-80 years

##### Exclusion criteria:

not share for study

##### Age

No age limit

##### Gender

Both

## Phase

2

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

N/A

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Other

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

دانشگاه علوم پزشکی بابل

##### Street address

Babol university of medical sciences- Shahid Ghasemi street

##### City

Babol

##### Province

Mazandaran

##### Postal code

47745-47176

#### Approval date

2018-07-07, 1397/04/16

#### Ethics committee reference number

IR.MUBABOL.REC.1397.035

## Health conditions studied

### 1

#### Description of health condition studied

TINNITUS

#### ICD-10 code

H93.1

#### ICD-10 code description

Tinnitus

## Primary outcomes

### 1

#### Description

effect of zinc sulfate on blood lipid changes in patients

with tinnitus correction

## Timepoint

before and after of intervention

## Method of measurement

with commercial kit

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

blood sample will collect for zinc and lipids concentration from all patient with tinnitus after preamble and their satisfaction. then zinc sulfate 220 mg (in all patient from one company) will administrated for 30 days daily. patient will evaluated after 30 days.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Aeatollah Rohani hospital

##### Full name of responsible person

Keyvan Kiakojoori

##### Street address

Shahid Ghasemi

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Babol University of Medical Sciences

##### Full name of responsible person

Reza Ghadimi

##### Street address

Shahid Ghasemi

##### City

Babol

##### Province

Mazandaran

##### Postal code

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**Phone**  
+98 11 3219 7667  
**Email**  
rezaghadimi@yahoo.com  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Babol 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**  
Babol University of Medical Sciences  
**Full name of responsible person**  
Hossein Najafzadehvarzi  
**Position**  
professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

not more information

### 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

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available