

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The impact of the herbal compound of corcomin- piperin and gingerol on Sudden sensorineural hearing loss in diabetic patients referred to Tehran Amir Alam and Khomeini Hospitals

#### Protocol summary

##### Summary

Aim of study: The aim of this study was to determine the effect of curcumin, piperine and gingerol component on hearing repair in diabetic patient with Sudden Sensorineural Hearing Loss Inclusion criteria: Type 2 diabetic patients with Sudden Sensorineural Hearing Loss in the age group of 20-65. Exclusion criteria: Presence of any cardiovascular disease, gastrointestinal disease, hypoglycaemia history , History of anticoagulant therapy, pregnancy and Lactation The study population: Diabetic patient with Sudden Sensorineural Hearing Loss referred to Amir-Alam and Vali- Asr hospitals Sample size: 51 cases Intervention: This study will have 3 arms , The first arm included patients will be eligible for injection 0.3-0.5 ml dexamethasone twice a week over six times in the middle ear with consume placebo capsules two a day for two months. The second arm included patients will be eligible for injection 0.3-0.5 ml dexamethasone twice a week over six times in the middle ear with consume Mixodin capsules ( 300 mg of curcumin , 3.25 mg Piperine and 7.5 mg of gingerol) one a day and consume placebo capsules one a day for two months. The third arm included patients will be eligible for injection 0.3-0.5 ml dexamethasone twice a week over six times in the middle ear with consume Mixodin capsules (300 mg of curcumin , 3.25 mg Piperine and 7.5 mg of gingerol) two a day for two months. Primary outcome measure: Changes in hearing threshold

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017012332132N1**

Registration date: **2017-05-05, 1396/02/15**

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

Last update:

Update count: **0**

##### Registration date

2017-05-05, 1396/02/15

##### Registrant information

###### Name

Ali Reza Karimi Yazdi

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6658 1628

###### Email address

karimiya@sina.tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2017-04-09, 1396/01/20

##### Expected recruitment end date

2017-10-12, 1396/07/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The impact of the herbal compound of corcomin- piperin and gingerol on Sudden sensorineural hearing loss in diabetic patients referred to Tehran Amir Alam and Khomeini Hospitals

##### Public title

The impact of the herbal compound of Turmeric- Black pepper and ginger extract on Sudden sensorineural hearing loss in diabetic patients

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: Type 2 diabetic patients with Sudden Sensorineural Hearing Loss in the age group of 20-65 y.

Exclusion criteria: Presence of any cardiovascular disease; gastrointestinal disease; Hypoglycemia; History of anticoagulant therapy; Pregnancy; and Lactation

#### **Age**

From **20 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **51**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Triple blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

51

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Tehran University of Medical Science

###### **Street address**

Keshavarz, BLV

###### **City**

ENT Research Center, Amir-Alam hospital, Imam Khomeini Hospital Complex. Keshavarz Blvd. Tehran, Iran

###### **Postal code**

##### **Approval date**

2016-12-20, 1395/09/30

##### **Ethics committee reference number**

IR.TUMS.VCR.REC.1395.1271

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Sudden Sensorineural Hearing Loss

##### **ICD-10 code**

H91.2

##### **ICD-10 code description**

Sudden idiopathic hearing loss

### **Primary outcomes**

#### **1**

##### **Description**

Changes in hearing threshold

##### **Timepoint**

Before the intervention, sixth week, third week, eighth week after the intervention

##### **Method of measurement**

examination, interview, audiometry

### **Secondary outcomes**

#### **1**

##### **Description**

Tinnitus

##### **Timepoint**

before intervention, The third week, sixth and eighth

##### **Method of measurement**

Examination and interview

#### **2**

##### **Description**

Dizziness

##### **Timepoint**

Before the intervention, the third week, sixth and eighth

##### **Method of measurement**

Examination and interview

### **Intervention groups**

#### **1**

##### **Description**

The first group included patients will be eligible for injection 0.3-0.5 ml dexamethasone twice a week over six times in the middle ear with consume placebo capsules two a day for two months

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

The second group included patients will be eligible for injection 0.3-0.5 ml dexamethasone twice a week over six times in the middle ear with consume Mixodin capsules( 300 mg of curcumin 3.25 mg Piperine and 7.5 mg of gingerol) one a day and consume placebo capsules one a day for two months

**Category**

Treatment - Drugs

**3****Description**

The third group included patients will be eligible for injection 0.3-0.5 ml dexamethasone twice a week over six times in the middle ear with consume Mixodin capsules( 300 mg of curcumin , 3.25 mg Piperine and 7.5 mg of gingerol) two a day for two months

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Valiasr hospital

**Full name of responsible person**

Dr.Ali Reza Karimi Yazdi

**Street address****City**

Tehran

**2****Recruitment center****Name of recruitment center**

Amiralam hospital

**Full name of responsible person**

Dr.Ardavan Taj dini

**Street address****City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

masud yunesian

**Street address**

Tehran University of Medical Scinces, Ghods squareTehran, Iran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Sciences

**Proportion provided by this source**

100

**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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr.Leyla Sahebi

**Position**

Assistant profesor

**Other areas of specialty/work****Street address**

Tehran

**City**

Tehran

**Postal code****Phone**

+98 21 6658 1628

**Fax****Email**

sahebileila@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran university of medical sciences

**Full name of responsible person**

Alireza Karimi Yazdi

**Position**

professor

**Other areas of specialty/work****Street address**

ENT research centert, Vali-Asr hospital, Imam Khomeini complex hospital, Tehran,Iran.

**City**

Tehran

**Postal code****Phone**

+98 21 6658 1628

**Fax****Email**

karimiya@sina.tums.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Leyla Sahebi

**Position**

Assistant professor

**Other areas of specialty/work****Street address**

ENT research center, Vali-Asr hospital, Imam Khomeini complex hospital, Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+216 581628

**Fax**

+216 581628

**Email**

sahebileila@yahoo.com

**Web page address****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*