

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effects of N-Acetylcysteine and Ginseng on Prevention of Noise Induced Hearing Loss in male workers

Protocol summary

Summary

The goal of this randomized clinical trial is evaluation of the effects of N-Acetylcysteine and Ginseng on prevention of Noise Induced Hearing Loss (NIHL). Inclusion criteria include Male workers; hearing better than 40 dBHL; ear health; no using of ototoxic drugs or food supplements or magnesium and exclusion criteria include male workers more than 50 years; hearing loss more than 40 dBHL; pathology of external, middle or inner ear and use of ototoxic drugs or food supplements or magnesium. In 48 factory male workers which are exposed to continuous noise, audiometry, high frequency audiometry, tympanometry and otoacoustic emission (OAE) will be measured prior to a work shift. Then these workers will be divided randomly into 3 groups. One group (case) will receive Acetylcysteine for two weeks, the other group (case) will receive Ginseng for two weeks and the last one will not receive any drug. After two weeks, measurements will be repeated. This study will perform from February until March 2013 in textile factory. Primary outcomes are hearing threshold and otoacoustic emission amplitude.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301158698N9**
Registration date: **2013-03-08, 1391/12/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-03-08, 1391/12/18

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

University of Social Welfare and Rehabilitation

Expected recruitment start date

2013-02-06, 1391/11/18

Expected recruitment end date

2013-03-14, 1391/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of N-Acetylcysteine and Ginseng on Prevention of Noise Induced Hearing Loss in male workers

Public title

Effect of N-Acetylcysteine and Ginseng on prevention of noise Induced Hearing Loss

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Male worker; Hearing better than 40 dBHL; Ear Health; No using of ototoxic drugs or food supplements or magnesium; Continuous noise more than 80 dBA in work place
Exclusion criteria: Male workers

more than 50 years; Hearing Loss more than 40 dBHL;
Pathology of external, middle or inner ear; Use of
ototoxic drugs or food supplements or magnesium;
Continuous noise less than 80 dBA in work place

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

University of Social Welfare and Rehabilitation
Sciences

Street address

Koodakiar street, Daneshjoo Blvd, Evin

City

Tehran

Postal code

Approval date

2013-01-27, 1391/11/08

Ethics committee reference number

26246

Health conditions studied

1

Description of health condition studied

Noise Induced Hearing Loss

ICD-10 code

H83.3

ICD-10 code description

Noise effects on inner ear

Primary outcomes

1

Description

Hearing threshold

Timepoint

Before Intervention, Two weeks after intervention

Method of measurement

Audiometer Instrument

Secondary outcomes

1

Description

Otoacoustic Emission amplitude

Timepoint

Before Intervention, Two weeks after intervention

Method of measurement

Otoacoustic emission Instrument

Intervention groups

1

Description

administration of N-Acetylcysteine tablets 600 mg oral 2
numbers for one time a day during two weeks and
Ginseng capsule 100 mg 2 numbers for one time a day
during two weeks (case group)

Category

Treatment - Drugs

2

Description

No administration of drug (control group)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Azadi textile factory

Full name of responsible person

Ahmad Hoorzad

Street address

Azadi square, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Social Welfare and Rehabilitation
Sciences

Full name of responsible person

Safamanesh

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Koodakiar street, Daneshjoo Blvd, Evin

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of Social Welfare and Rehabilitation 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

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Other areas of specialty/work

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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