

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of applying different permissible exposure limits in preserving hearing threshold level among automobile industry workers: An intervention study

Protocol summary

Summary

The aim of this study is to assess the effectiveness of applying different permissible exposure limits (90 in Factory 1 with 85 dBA in Factory 2) in preserving the hearing threshold and preventing the development of temporary Standard Threshold Shift (currently 90 dBA is adopted). The inclusion criterion is subjects who were exposed to levels above action level, either 85 or 80 dBA in Factory 1 and Factory 2, respectively. The exclusion criteria are those refused to participate, contract workers, workers suffering from diseases of ear, physical trauma to ear, lorry drivers (not stationed in the factories), workers who had undergone ear surgery and who were diagnosed to have congenital hearing loss. The study population is the general workers from the two factories in an automobile industry. The sample size required is 52 workers in each factory. Noise level was measured using a personal exposure noise dosimeter and a sound level meter. The hearing threshold levels were measured at baseline and then followed up at the first month (post-shift exposure) and again, on the sixth month. Data on hearing threshold levels were measured using a manual audiometer. Hearing protection devices with appropriate noise reduction rate were used to reduce noise exposure among participants (in Factory 1, the aim is between 85 and 90 dBA while in Factory 2 is between 80 and 85 dBA). The primary outcome is to measure the mean hearing threshold levels, hearing threshold levels beyond 25 dBA and standard threshold shifts among participants between the two factories.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121515783N1**
Registration date: **2013-12-30, 1392/10/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-30, 1392/10/09

Registrant information

Name

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Name of organization / entity

University of Malaya

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Recruitment status

Recruitment complete

Funding source

from University of Malaya

Expected recruitment start date

2012-02-01, 1390/11/12

Expected recruitment end date

2012-08-15, 1391/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of applying different permissible exposure limits in preserving hearing threshold level among automobile industry workers: An intervention

study

Public title

The effectiveness of exposure to different sound levels in preserving hearing

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterion is subjects exposed to noise levels above action level (85 dBA in one factory and 80 dBA in another factory). Exclusion criteria are refused to participate, contract workers, who have diseases of ear, impacted wax, perforated tympanic membrane, physical trauma to ear, lorry drivers, who had undergone ear surgery and those have congenital hearing loss.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 104

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

The statistician was also blinded except the researchers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee, University Malaya Medical Centre

Street address

University of Malaya, Jalan Universiti

City

Kuala Lumpur

Postal code

50603

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

848.37

Health conditions studied

1

Description of health condition studied

Prevention of Noise-induced hearing loss

ICD-10 code

H83.3

ICD-10 code description

Noise-induced hearing loss

Primary outcomes

1

Description

Hearing threshold level

Timepoint

Six months

Method of measurement

Using manual audiometer

Secondary outcomes

1

Description

measuring knowledge, attitude and practice on noise-induced hearing loss

Timepoint

Six months

Method of measurement

Through questionnaire

Intervention groups

1

Description

Intervention (as control arm)- On Factory 1, Hearing protection devices were used to reduce noise exposure level between 85 and 90 dBA, based on noise reduction rate (currently adopted by the factory)

Category

Prevention

2

Description

Second arm (Intervention)- Hearing protection devices were used to reduce noise exposure level between 80 and 85 dBA

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Toyota Auto Body (M) Sdn. Bhd.
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Post Graduate Research Grant University of Malaya
Full name of responsible person
Associate Prof. Dr. Moy Foong Ming
Street address
Department of Social and Preventive Medicine,
Faculty of Medicine Building, University of Malaya
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Kuala Lumpur
Grant name
Grant code / Reference number
PV106/2011A
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Post Graduate Research Grant University of Malaya
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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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