Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of acute industrial noise effects on blood pressure and heart rate in comparison with musical sound

Protocol summary

Summary

The aim of this crossover clinical trial is to compare acute effect of musical and industrial sound exposure on blood pressure and heart rate. The subjects will be chosen from 20- 40 aged volunteer men with normal blood pressure and hearing. Subjects with diabetes, antihypertensive drug use or any other condition that can affect blood pressure and/or heart rate will be excluded from the study. Subjects will be assigned randomly (balanced block Randomization) into one of two groups. Each group will be exposed in a cross-over manner either to industrial noise (90dBA textile industry noise) or light music (90dBA love is blue music sound). During exposure time, systolic and diastolic blood pressure and heart rate will be monitored.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811143269N1**
Registration date: **2010-04-24, 1389/02/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-04-24, 1389/02/04

Registrant information

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Gholamreza Pouryaghoub
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences and Health Services, Vice chancellor for Research

Expected recruitment start date

2010-04-20, 1389/01/31

Expected recruitment end date

2010-06-21, 1389/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of acute industrial noise effects on blood pressure and heart rate in comparison with musical sound

Public title

Industrial noise and music sound effects on blood pressure and heart rate; a randomized trial

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: volunteer men aged 20-40 with normal blood pressure and normal hearing (verified with eudiometry). Exclusion criteria: Consumption of anti hypertensive medication, history of cardiovascular disease or diabetes mellitus, caffeine intake within 1h before baseline measurement, smoking in 15 minutes before baseline measurement, external adrenergic stimulant consumption (such as intra nasal decongestant) and inadequate sleep during previous night

Age

From **20 years** old to **40 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences and Health Services

Street address

Tehran University of Medical Sciences and Health Services, Poorsina street. Tehran

City

Tehran

Postal code

Approval date

2010-01-22, 1388/11/02

Ethics committee reference number

6338

Health conditions studied

1

Description of health condition studied

blood pressure and heart rate

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Blood Pressure

Timepoint

Every 5 minute during exposure

Method of measurement

by digital sphygmomanometer OMRON 907

2

Description

heart rate

Timepoint

Every minutue during exposure

Method of measurement

by digital sphygmomanometer OMRON 907

Secondary outcomes

1

Description

Hearing transient Threshold Shift

Timepoint

just before and after exposure

Method of measurement

audiometery

Intervention groups

1

Description

15 minute exposure with 90dBA music sound in control group

Category

Other

2

Description

15 minute exposure with 90dBA industrial noise in intervention group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Baharloo Hospital

Full name of responsible person

Gholamreza Pouryaghoub

Street address

Baharloo Hospital. Rah Ahan Squ.

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
Deputy of Research
Street address
Tehran University of Medical Sciences, Porsina Street, Tehran
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 and Health Services
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