

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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

##### Name

Gholamreza Pouryaghoub

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6640 5588

##### Email address

pourya@tums.ac.ir

##### 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 audiometry). 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**

audiometry

**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****Name of organization / entity**

Tehran University of Medical Sciences and Health Services

**Full name of responsible person**

Gholamreza Pouryaghoub

**Position**

Occupational Medicine Specialist/ Faculty Member

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

Occupational Medicine Department, School of Medicine, Tehran University of Medical Sciences and Health Services

**City**

Tehran

**Postal code****Phone**

+98 21 6640 5588

**Fax****Email**

pourya@tums.ac.ir

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Tehran University of Medical Sciences and Health Services

**Full name of responsible person**

Gholamreza Pouryaghoub

**Position**

Occupational Medicine Specialist,

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

Occupational Medicine Department. School of Medicine, Tehran University of Medical Sciences and Health Services

**City**

Tehran

**Postal code****Phone**

+98 21 6640 5588

**Fax****Email**

pourya@tums.ac.ir

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Tehran University of Medical Sciences and Health Services

**Full name of responsible person**

Gholamreza Pouryaghoub

**Position**

Occupational Medicine Specialist/Faculty Member

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

Occupational Medicine Department, School of Medicine, Tehran University of Medical Sciences and Health Services

**City**

Tehran

**Postal code****Phone**

+98 21 6640 5588

**Fax****Email**

pourya@tums.ac.ir

**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*