

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Determining saliva cortisol level response to noise exposure in a RCT study

Protocol summary

Summary

To evaluate the saliva cortisol level response to stress effect of noise exposure, with respect to inclusion and exclusion criteria 100 volunteers will be introduced to study. They will be allocated to intervention and control groups randomly using balanced block randomization method. After saliva sampling (before intervention sample) intervention group will experience 20 minute exposure to 90 dB industrial noise (controlled with SLM) in sitting position without any physical activity in a controlled room. Control group will experience same condition without noise exposure. After this period second saliva sampling will be down. Finally saliva cortisol alternation will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111163269N2**

Registration date: **2011-12-11, 1390/09/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-12-11, 1390/09/20

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, Deputy of Research

Expected recruitment start date

2011-12-22, 1390/10/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining saliva cortisol level response to noise exposure in a RCT study

Public title

stress responses to noise exposure

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: male gender; normal hearing;
Exclusion criteria: age lower than 20 or higher than 40 years; cardiovascular diseases; diabetes; alcohol consumption; Hypertension; food consumption during 2hr before sampling; tea or cafe consumption during 30 minute before sampling; smoking during 30 minute before sampling; use of drugs that can alter corticosteroids secretion; previous night sleep deprivation; sport activity before sampling

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

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Deputy of Research, Tehran University of Medical Sciences

Street address

Enqelab Square, Qods Avenue, Tehran University of Medical Sciences Central Office

City

Tehran

Postal code**Approval date**

2010-11-07, 1389/08/16

Ethics committee reference number

1085/130/89/ص

Health conditions studied**1****Description of health condition studied**

saliva cortisole increase

ICD-10 code

Z57.0

ICD-10 code description

occupational noise exposure

Primary outcomes**1****Description**

saliva cortisol increase

Timepoint

just before and after intervention

Method of measurement

using saliva cortisol dimetra kit

Secondary outcomes

empty

Intervention groups**1****Description**

Exposure to 90 dB recorded industrial noise for a 20 minute interval without any physical activity at sitting position in a controlled room for intervention group.

Category

Other

2**Description**

sitting in a controled room for 20 minute without any physical activity (same experience as intervention group) without noise exposure.

Category

Other

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

Baharloo Haspital

Full name of responsible person

Gholamreza Pouryaghoub

Street address

Tehran Rah Ahan Square

City

Tehran

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

Thran University of Medical Sciences

Full name of responsible person

Deputy of Research

Street address

Enqelab Square, Qods Avenue, Tehran University of Medical Sciences Central Office, Deputy of Research

City

Tehran

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

Yes

Title of funding source

Thran 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

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Person responsible for general inquiries

Contact

Name of organization / entity
Center for Research on Occupational Diseases
Full name of responsible person
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Position
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Other areas of specialty/work
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Person responsible for updating data

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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