Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Scienses
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 Scienses
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

Center for Research on Occupational Diseseas

Full name of responsible person

Gholamreza Pouryaghoub

Position

Occupational medicine specialist

Other areas of specialty/work

Street address

Center for Research on Occupational Diseases,
Tehran University of Medical Sciences

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

Center for Research on Occupational Diseases

Full name of responsible person

Gholamreza Pouryaghoub

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Occupational medicine specialist

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Person responsible for updating data

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