Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the traffic noise effect on saliva cortisol and alpha amylase during driving activity

Protocol summary

Summary

The present study was designed to evaluate the effect of traffic noise on salivary bio-markers while driving activity was ongoing. In order to implement the project we employ male students who have driving license and also driving experience. We ask these people to stay on a car that is capable to simulate driving activity and drive with it for an hour. During driving, in the laboratory we will display the recorded traffic noise with sound average level of 75 dBA. As the previous studies showed that noise can release stress hormones in body, thus in this study in order to deliberate the effect of noise on people performance, effect of noise on stress hormones , such as cortisol and alpha amylase will be checked. This means that the level of these hormones once before and once after testing by individuals,will be measured to determine the effect of noise on hormone levels. In this study we use salivary cortisol and alpha-amylase kits to collect samples once before and once after driving activity and the samples will send to the laboratory for analysis. Sample size is 56 persons for cortisol and alpha amylase and these people in each stages of study can leave this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110424875N1**
Registration date: **2016-01-12, 1394/10/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-01-12, 1394/10/22

Registrant information

Name

Iraj alimohammadi

Name of organization / entity

iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Governmental sources of Iran University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the traffic noise effect on saliva cortisol and alpha amylase during driving activity

Public title

Effect of traffic noise on saliva cortisol and alpha amylase during driving

Purpose

Prevention

Inclusion/Exclusion criteria

Healthy men; aged between 18 to 35 years old; without any underlying disease and medicine consumption or smoke; having driving licence and driving experience; fill the form of participating in the project exclusion criteria:

Unwillingness to continue cooperation

Age
From **18 years** old to **35 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Sciences

Street address
Iran, Tehran, Hemmat highway, Next to Milad Hospital, Iran University of Medical Science

City
Tehran

Postal code

Approval date
2015-09-22, 1394/06/31

Ethics committee reference number
IR.IUMS.REC.1394.26225

Health conditions studied

1

Description of health condition studied
The effect of traffic noise on secretion of cortisol and alpha amylase

ICD-10 code
-

ICD-10 code description
-

Primary outcomes

1

Description
saliva level of cortisol

Timepoint
during experiments before samples be exposed with recorded traffic noise and doing driving activity

Method of measurement
by cortisol and alpha amylase kits

Secondary outcomes

1

Description
level of saliva alpha amylase

Timepoint
after finishing each level of experiment

Method of measurement
by cortisol and alpha amylase kit

Intervention groups

1

Description
In order to determining the effects of noise on stress hormones, people will expose to recorded traffic noise during driving activity. The levels of stress hormones such as cortisol and alpha amylase, as stress index before and after doing experiments will be measured.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Iran University of Medical Sciences

Full name of responsible person
Iraj Almohammadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research manager of Iran University of Medical Science

Full name of responsible person
Dr Naserbakht

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Iran, Tehran, Hemmat highway, Next to Milad Hospital, Iran University of Medical Science

City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research manager of Iran University of Medical Science
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

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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