Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

Evaluating performance of facemasks in reducing ambient particulate matter (PM10، PM2.5، PM1) exposure and theirs wearing on acute cardiovascular effects: A Randomized crossover trial

Protocol summary

Study aim
Evaluating effectiveness of using facemasks on acute cardiovascular effects
Design
We will conduct a randomized crossover trial among 30 healthy college students at Tehran university of medical sciences from 24 January 2019 to 7 February 2019. These students live in dormitory that are randomized into 2 groups (15 subjects for each group) and alternate the use of/or without wearing particulate-filtering facemask for 48h with a 2-week washout interval.
Settings and conduct
Please see above.
Participants/Inclusion and exclusion criteria
college students with no history of tobacco smoking (never smokers) or alcohol addiction, no clinically diagnosed chronic cardiopulmonary diseases and no recent infections.
Intervention groups
Wearing particulate-filtering respirators Without particulate-filtering respirators
Main outcome variables
Heart Rate Variability Blood pressure Biomarkers of hs-cTnT and NT-proBNP

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181214041961N1**
Registration date: **2019-01-14, 1397/10/24**
Registration timing: **prospective**

Last update: **2019-01-14, 1397/10/24**
Update count: **0**
Registration date
2019-01-14, 1397/10/24

Registrant information
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Kazem Naddafi
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-01-24, 1397/11/04
Expected recruitment end date
2019-02-06, 1397/11/17
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating performance of facemasks in reducing ambient particulate matter (PM10، PM2.5، PM1) exposure and theirs wearing on acute cardiovascular effects: A Randomized crossover trial

Public title
Cardiovascular Benefits of Wearing Particulate-Filtering facemasks
Purpose
Prevention
Inclusion/Exclusion criteria

Inclusion criteria:
no history of tobacco smoking (never smokers) no alcohol addiction no clinically diagnosed chronic cardiopulmonary diseases no recent infections
Exclusion criteria:

Age
From **20 years** old to **30 years** old

Gender
Male

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

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

Street address
Qods st, Blvd Keshavarz

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2018-11-13, 1397/08/22

Ethics committee reference number
IR.TUMS.SPH.REC.1397.163

Health conditions studied

1

Description of health condition studied
acute cardiovascular effects

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Heart rate variability

Timepoint
Heart rate variability will be continuously monitored during the 2nd 24 hr in each intervention.

Method of measurement
A 12-lead continuous electrographic Holter monitor will be used.

2

Description
Blood pressure

Timepoint
Blood pressure will be continuously monitored during the 2nd 24 hr in each intervention.

Method of measurement
A portable and automated ambulatory BP monitoring and recording instrument will be used.

3

Description
Biomarkers of NT-proBNP and hs-cTnT

Timepoint
A venous blood sample will be collected at the end of ecah intervention in order to examine the level of each above-mentioned biomarkers.

Method of measurement
They will be measured using enzyme-linked immunosorbent assays.

Secondary outcomes

empty

Intervention groups

1

Description
Wearing particulate-filtering facemask

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran Heart Center

Full name of responsible person
Masih Tajdini

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North Kargar-Ave

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran National Science Foundation
Full name of responsible person
-
Street address
33, 5th St., North Kargar St.
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Postal code
1439634665
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environment@insf.org
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran National Science Foundation
Proportion provided by this source
45
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Other

2

Sponsor
Name of organization / entity
Tehran Heart Center
Full name of responsible person
Saeed Sadeghian
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran Heart Center
Proportion provided by this source
55
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Masih Tajdini
Position
Assisstant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
These information will be published at the report and article of the current study.

When the data will become available and for how long
After the end of study

To whom data/document is available
Researchers Policy-makers

Under which criteria data/document could be used
with referencing

From where data/document is obtainable
Sasan Faridi Mohammad Sadegh Hassanvand

What processes are involved for a request to access data/document
-

Comments