

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

2019-01-14, 1397/10/24

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

Registrant information

Name

Kazem Naddafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 4914

Email address

knadafi@tums.ac.ir

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 each 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

Street address

North Kargar-Ave

City

Tehran

Province
Tehran
Postal code
1411713138
Phone
+98 21 8802 9600
Email
masihtajdini@gmail.com

Postal code
1411713138
Phone
+98 21 8802 9600
Fax
+98 21 8802 9731
Email
sadeghian@tums.ac.ir

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.
City
Tehran
Province
Tehran
Postal code
1439634665
Phone
+98 21 8216 1157
Email
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
Street address
North Kargar-Ave , Tehran-Iran
City
Tehran
Province
Tehran

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
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
North Kargar-Ave
City
Tehran
Province
Tehran
Postal code
1411713138
Phone
+98 21 6643 7147
Email
Drmasih84@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Sadegh Hassanvand
Position

Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Environmental Health
Street address
Center for Air Pollution Research, 8th Floor, No. 1547,
North Kargar Avenue, Tehran I.R. Iran
City
Tehran
Province
Tehran
Postal code
1417993362
Phone
+98 21 8897 8395
Fax
+98 21 8897 8398
Email
Hassanvand@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sasan Faridi
Position
Ph.D candidate
Latest degree
Master
Other areas of specialty/work
Environmental Health
Street address
Center for Air Pollution Research, 8th Floor, No. 1547,
North Kargar Avenue, Tehran I.R. Iran
City
Tehran
Province
Tehran
Postal code
1417993362

Phone
+98 21 8897 8395
Fax
+98 21 8897 8397
Email
Sasanfaridi67@gmail.com

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
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Comments