

# 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/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

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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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**Province**  
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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

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  
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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  
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Specialist  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**