

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of serum oxygen level following the use of three-layer, five-layer and n95 masks after intervals of 1,2,3 hours in dental students

Protocol summary

Evaluation of blood serum oxygen before usage and then after 1, 2 and 3 hours usage of face mask.

Study aim

Evaluation of serum oxygen level after using five-layer ,three-layer and n95 face masks after 1, 2 and 3 hours in dental students

Design

This cross-sectional analytical study was performed on 38 dental students of Islamic Azad University in 1401-1400 will be. Students will enter the study based on entry and exit criteria. Age and gender of students Will be registered

Settings and conduct

This cross-sectional study will be performed on 38 dental students of Islamic Azad University in 2021-2022. Students will enter the study based on entry and exit criteria. Students' age and gender will be recorded. Their arterial oxygen percentage will be measured 22 minutes before the start of the study and at rest using a pulse oximeter, Datascope (Passport 2), USA. The pulse oximeter shows the average pulse oximeter every five seconds. Pulse oximeter probe to the finger that makes the best wave Will be connected. The finger should be clean and free of henna, paint or tattoos and should not be cold. This study will be done in three days.

Participants/Inclusion and exclusion criteria

Entry Conditions : Complete health and satisfaction in the study No entry conditions: Heart, respiratory, kidney disease and smoking

Intervention groups

Control group: Evaluation of blood serum oxygen before usage of 3-layer, 5-layer and N95 face mask .
Intervention group 1: Students are asked to put a three-layer mask on their face. After 1, 2 and 3 hours, their arterial oxygen level will be measured. Intervention group 2: Students are asked to put a five-layer mask on their face. After 1, 2 and 3 hours, their arterial oxygen level will be measured. Intervention group 3: Students are asked to put a N95 mask on their face. After 1, 2 and 3 hours, their arterial oxygen level will be measured.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211021052832N1**

Registration date: **2021-11-16, 1400/08/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-16, 1400/08/25**

Update count: **0**

Registration date

2021-11-16, 1400/08/25

Registrant information

Name

Ebrahim Fakouri joybari

Name of organization / entity

Azad tehran dental university

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 9758

Email address

ebi.fakouri1987@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-07, 1400/08/16

Expected recruitment end date

2021-11-19, 1400/08/28

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Evaluation of serum oxygen level following the use of three-layer, five-layer and n95 masks after intervals of 1,2,3 hours in dental students

Public title
The effect of the mask on blood oxygen

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Complete health satisfaction in the study

Exclusion criteria:
Heart, respiratory, kidney disease, smoking

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the School of Dentistry, Islamic Azad University of Medical Sciences

Street address
No. 9, Neyestan 9th alley, Pasdaran Avenue, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1946853314

Approval date

2021-10-25, 1400/08/03
Ethics committee reference number
IR.IAU.DENTAL.REC.1400.081

Health conditions studied

1

Description of health condition studied
Blood serum oxygen level changes after using face masks.

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood serum oxygen level before usage of 3-layers, 5-layers and N95 face masks.

Timepoint
Before usage of 3-layers, 5-layers and N95 face masks.

Method of measurement
Pulse oximetry

2

Description
Blood serum oxygen level after 1 hour usage of 3-layers, 5-layers and N95 face masks.

Timepoint
After usage of 3-layers, 5-layers and N95 face masks for 1 hour.

Method of measurement
Pulse oximetry

3

Description
Blood serum oxygen level after 2 hours usage of 3-layers, 5-layers and N95 face masks.

Timepoint
After usage of 3-layers, 5-layers and N95 face masks for 2 hour.

Method of measurement
Pulse oximetry

4

Description
Blood serum oxygen level after 3 hours usage of 3-layers, 5-layers and N95 face masks.

Timepoint
After usage of 3-layers, 5-layers and N95 face masks for 3 hour.

Method of measurement
Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Control group 1: Blood Serum oxygen level in students is measured before applying the face mask.

Category

N/A

2

Description

Intervention group 1: Students are asked to put a three-layer mask (Rainik, Iran) on their face. After 1, 2 and 3 hours, their arterial oxygen level will be measured by pulse oximeter. In the meantime, the mask will not be removed from the students' faces.

Category

Prevention

3

Description

Intervention group2 : Students are asked to put a Five-layer mask (Rainik, Iran) on their face. After 1, 2 and 3 hours, their arterial oxygen level will be measured by pulse oximeter. In the meantime, the mask will not be removed from the students' faces.

Category

Prevention

4

Description

Intervention group 3: Students are asked to put a N95 mask (Mellat Bloon, Iran) on their face. After 1, 2 and 3 hours, their arterial oxygen level will be measured by pulse oximeter. In the meantime, the mask will not be removed from the students' faces.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive treatment department of the dental school

Full name of responsible person

Ebrahim fakouri juibary

Street address

No. 9, Neyestan 9th alley, Pasdaran Avenue, Tehran, Iran

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Postal code

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Phone

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Email

Ebi.fakouri1987@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ebrahim Fakouri Jouybari

Street address

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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

Islamic Azad University

Proportion provided by this source

100

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

Islamic Azad University

Full name of responsible person

Ebi Fakouri Jouybari

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Alireza Makkinejad
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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