Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of using an automatic masking device on the contamination rate of masks.

Protocol summary

Study aim
Determining and comparing the effect of using an automatic masking device by removing the mask from the basket on the contamination rate of the masks.

Design
The present study is a clinical trial with a control group, with parallel groups, one-way blind. 120 people will be selected with easy access and will be divided into two equal groups by stratified random block allocation method.

Settings and conduct
The intervention site is the operating room of Ayatollah Kashani Hospital in Isfahan. The research is one-way blind and the statistical analyst does not know the study groups.

Participants/Inclusion and exclusion criteria
Operating room personnel with associate degree, bachelor's and master's degree in operating room, anesthesia, nursing, residents and orthopedic surgery and neurosurgery, insensitivity of the sample to fluorescent powder and participation in surgery for at least one hour.

Intervention groups
Personnel are divided into two groups, A and B. After washing the hands in the standard way, the personnel first take 3 grams of fluorescent powder from a third person who also wears sterile gloves, and with both hands (palm and back of the hand and Between the fingers) they clap from the fingertips to the wrists, and then staff A removes the mask from the basket, and staff B receives the mask.

Main outcome variables
Area of glitterbug powder on surgical masks

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150715023216N11**
Registration date: **2022-01-16, 1400/10/26**
Registration timing: **retrospective**

Last update: **2022-01-16, 1400/10/26**
Update count: **0**

Registration date
2022-01-16, 1400/10/26

Registrant information

Name
Said Amini Rarani

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 31 3522 6158

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ghadami@mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-19, 1400/09/28

Expected recruitment end date
2022-01-09, 1400/10/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of using an automatic masking device on the contamination rate of masks.

Public title

Comparison of contamination between two methods of distributing surgical masks among personnel.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Operating room staff with associate, bachelor's and master's degrees in operating room, anesthesia and nursing. Residents and surgeons in surgery, orthopedics and neurology. Insensitivity of the sample to fluorescent powder. Participate in surgery for at least one hour.

Exclusion criteria:

People are not satisfied to participate in the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using the available sampling method, the operating room and anesthesia and nursing staff of the operating room and the operating room, neurology and orthopedics are selected and their inclusion criteria are reviewed. The selection of personnel according to the inclusion criteria and random allocation in a layered block method are placed in two groups A and B. Group A removes the mask from the basket, group B receives the mask from the device. Sampling continues until the required sample size in each group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The statistical analyst does not know what group each sample belongs to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Hazar Jarib Street

City

Esfahan

Province

Isfehan

Postal code

۸۱۷۴۶۷۳۴۶۵

Approval date

2021-12-18, 1400/09/27

Ethics committee reference number

IR.MUI.NUREMA.REC.1400.186

Health conditions studied

1

Description of health condition studied

Self-contamination of personnel

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Areas containing glitterbug powder on surgical Mask that indicate contamination will be measured.

Timepoint

before the intervention and one hour after intervention

Method of measurement

by using image j app

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Group A personnel are considered as control group. After washing the hands in the standard way, the personnel first take 3 grams of fluorescent powder from a third person who also wears sterile gloves and apply it to both hands (palm and back of the hand and between the fingers) from the fingertips to the wrists. And then personnel A remove the mask from the basket.

Category

Prevention

2

Description

Intervention group: Group B personnel are considered as intervention group. After washing the hands in the standard way, the personnel first take 3 grams of fluorescent powder from a third person who also wears sterile gloves and take it in both hands (foam and zinc). Behind the hand and between the fingers) from the fingertips to the wrists, then B personnel receive the surgical mask from the automatic masking machine

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Kashani hospital
Full name of responsible person
Dr Ahmad Ghadami
Street address
Ayatollah Kashani hospital, Kashani Street, Isfahan city, Isfahan province, Iran
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghayegh Haghjoo
Street address
Isfahan university of medical sciences, Hezar Jarib street, Isfahan city, Isfahan province, Iran
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Postal code
8174673461
Phone
+98 31 3792 3071
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
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
Esfahan University of Medical Sciences
Full name of responsible person
Dr Ahmad Ghadami
Position
PhD
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
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NO 127, 22 Bahman alley, Raran St, Khorasegan city, Isfahan province, Iran
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person
Ahmad Ghadami

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Individual participant data collected for the primary outcome measures

When the data will become available and for how long
After publication for one year

To whom data/document is available
For all people who request for data

Under which criteria data/document could be used
It is allowed to perform any analysis on the data, but use of data for publication is not allowed.

From where data/document is obtainable
Corresponding author of article

What processes are involved for a request to access data/document
After requesting the data by email to corresponding author , the data will be sent after a maximum period of one week

Comments