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Laboratory protocol

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thananda [1]

[1][Navamindradhiraj University]

1 Works for me dx.doi.org/10.17504/protocols.io.bnr2md8e

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N99: A novel and effective tool to prevent COVID-19

Protocol Number 1

Trial Registration

NCT044454606

Study conducted by
Navamindradhiraj University

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The National Research Council of Thailand ,The National Science Technology and Development Agency and Navamindradhiraj University.

Site Principle Investigator
Associate Professor Anan Manomaipiboon

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Investigator's Agreement Page

1. I have read the foregoing protocol and agree to conduct the study as outlined herein.
2. I agree to follow this protocol version as approved by the Ethics Review Committee/Institutional Review Board (ERC/IRB).
3. I agree this study will be conducted in accordance and in conformity with ICH GCP, the Declaration of Helsinki, and all applicable regulations.
4. I will conduct the study in accordance with applicable ERC/IRB requirements to maintain the protection of the rights and welfare of study participants.
5. I certify that I, and the study staff, have received the requisite training to conduct this research protocol.
6. I will not modify the protocol without first obtaining permission from the sponsor, an ERC/IRB approved amendment, and new protocol version, unless modification is necessary to protect the health and welfare of study participants.
7. I will ensure the data and/or specimens are maintained in accordance with the data and/or specimen disposition outlined in the protocol. Any modifications to this plan should first be reviewed and approved by the applicable ERC/IRB.
8. I will prepare and submit continuing review reports according to established timeframes at intervals established by the IRB and a study closure report when all research activities are completed.
9. I agree to maintain adequate and accurate records in accordance with institutional policies, local laws, and regulations as applicable.
10. I certify that the statements herein are true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept the responsibility for the scientific conduct of the project.

_____ _____

XXX (PI) DateXXX

Bitrex Qualitative fit test

Reference: https://www.moldex.com/pdf/misc/bitrex_fit_test_kit.pdf)
According to the manufacturer's instructions, we used the Bitrex fit test to ensure the good fit and seal of the respirator to the wearer. This fit test meets the performance criteria for fit testing respirators under current OSHA Standards.
- The equipment required are
1. Moldex Bitrex Qualitative Fit Test Kit
2. Moldex Bitrex Quantative Test Hood

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3. Nebulizer #1 (BITREX Sensitivity Solution)
4. Nebulizer #2 (BITREX Fit Test Solution)
6. BITREX Fit Test Solution Applicator Tube
7. BITREX Sensitivity Solution Applicator Tube
8. Appropriate Moldex Respirators*
5. Two sets Replacement Nebulizer Inserts

We followed the manufacturer guidelines as following;

1. Sensitivity screening

Each subject was given a taste-threshold screening testto ensure that he or she could taste Bitrex at the specified solution to make the fit test valid.

1) Ensure that the test subject does not eat, drink, smoke or chew gum for 15 minutes before the test.
2) Explain the screening and fit testing procedures to the subject.
3) Instruct subject to put on the hood without a respirator.
4) Position the hood forward so there is about six inches between the subject's face and the window. This is especially important for the fit test. It allows free movement of the head when the subject is wearing a respirator and helps ensure even dispersion of the aerosol around the face seal area.
5) Instruct the test subject to breathe with their mouth slightly open and tongue extended.
6) Using the nebulizer labeled BITREX Sensitivity Solution, inject the aerosol into the hood through the hole in front of the enclosure. Inject ten (10) squeezes of the bulb, fully collapsing and fully expanding the bulb on each squeeze.
7) Ask the subject if he can detect the bitter taste of BITREX.
8) If the subject does not detect bitter taste, inject an additional ten squeezes into the hood.
9) If the subject still does not detect bitter taste, inject an additional ten squeezes, for a total of 30 squeezes.
10) If 30 squeezes were inadequate to elicit a response from the subject, this subject cannot be fit tested with the BITREX test.
11) If the subject could detect bitter taste, the number of squeezes required to produce a taste response should be noted, i.e., 10, 20 or 30 squeezes, even if subject tasted the BITREX on a number of squeezes other than multiples of ten.
12) Remove the hood. Wait a few minutes, to give the subject time to clear the taste from his mouth, before proceeding to the fit test. A drink of water during this time will aid in removing the bitter taste. Use a paper towel to wipe the subject's mouth of any residue (also wipe mustaches).
The Fit test procedure

2. Fit test

1) Use any Moldex disposable N, R or P series class disposable respirator or any Moldex half mask or full face respirator with any N, R or P series filter. Have the test subject put on and adjust the respirator per the instructions provided with the respirator. Have the subject select the size respirator that provides the best fit. The subject may find a mirror useful in the adjustment process. The subject should wear the respirator at least five (5) minutes before starting the test.
2) Instruct the subject to put on and position the hood as before and breathe with their mouth slightly open and tongue extended.
3) Using the nebulizer labeled BITREX Fit Test Solution, inject the fit test aerosol into the hood. The same number of squeezes is required as was necessary to elicit a response in the threshold sensitivity screening test, i.e., 10, 20 or 30 squeezes.
4) To maintain an adequate concentration of aerosol during the test, one half of the initial number of squeezes should be injected again every 30 seconds (i.e., 5, 10, or 15) through out the test.
5) After injecting the aerosol initially, ask the test subject to perform the following exercises for 60 seconds each:
(a) Normal breathing.
(b) Deep breathing.
(c) Turning head from side to side, stopping at each end of travel for one or two breaths.
(d) Moving head up and down, stopping at each end of travel for one or two breaths.
(e) Talking, reciting the alphabet, or reading a prepared text (the Rainbow Passage is recommended, see below).
(f) Jogging in place.
(g) Normal breathing.
6) Instruct the subject to indicate if they detect the bitter taste at any time during
the test.
7) If the entire test is completed without the subject detecting the bitter taste of the aerosol, the test is passed and the respirator's fit on that individual is judged adequate.
8) At any time during the test, if the subject detects the bitter taste of the aerosol the test is stopped at this point. When this occurs, the fit of the respirator on the subject is judged inadequate.
9) If the test is failed, before retesting the subject, a 15-minute waiting period must be observed and the taste sensitivity screening test must be performed again. Test again with same Moldex model.
10) If the second test fails, repeat tests with another size and/or model Moldex respirator.

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11) Document results of fit tests for each employee

Filter Penetration Test

This test is the application from TSI Filter Tester Model 8130A to evaluate the N95 mask test according to the 42CFR part 84 standard. An equipment setup was constructed to measure the particle penetration respirators . Particle penetration of respiratorswas evaluated against sodium chloride aerosol size 0.3 micron. The air flow rate was kept constant at 85 ± 4 L/min andconcentration≤200 mg/m3

Equipment:
1. SIBATA MT-05U Fit test (With the OSHA standard at 29 CFR 1910.134 (Quantitative Fit Test).The machine counts particles size 0.3 µm with count range from0 -9999999particles and inflow suction rate of1 L/min . Filter facepiece respirator,FFR performance is measured by testing the FFR at a constant and high flow in one direction from the outside to the inside of the mask.
2. Particle Generator that generate particles size of more than 0.3 µm by ultrasonic mechanism
3. Sodium Chloride (NaCl)100 mg dilute in water650 ml together with particle generator to generate particles size more than 0.3 µm
4.Mixing Chamber to control the concentration ≤ 200 mg / m3 and particles flow rateto at 85 ± 4 L / min as standard by using the two Vacuum Pumps
We followed the protocol step by step:
1. Put the filter in the test filter chamber and hook to theFilter Holder by bringing the outsideupside down
2. Turn on the Aerosol generator and Vacuum Pump generators to deliver NaCl tablet to the Mixing Chamber. Aerosol particles were generated using 1.5%NaCl solution to get the concentration of less than 200 mg / m3 by using both vacuum pumps to control the Aerosol concentration at Flow Rate 85 ± 4 L / min.
3. The Fitting Test will suck the particles through the filter and measure the particles inside compare to the outside particles.
4. The particles sizes of average 0.3 µm were selected.
5. Turn on the Fitting Testing (SIBATA MT-05U Fit test) and turn on the Fit Test mode, read the Outside value measured particle before passing through the filter and Mask (Inside) is the filtered value. Where the resulting value is the number of particles
4. Record the results and perform process tests to find the average.
Percent penetration rate will be calculated according to the equation
(1- (Particle through the Filter / Ambient Particle)) x 100.
6. We tested the baseline filter performance (first use) and used the filters that used already between 1 and 24 h
.

The equation for processing filter efficiency

The equation to calculate the filter efficiency of a filter by percentage is as follows

Performance Filter (%) is the filtering efficiency percentage of a filter.
Inside is the number of particles after passing through the filter to be tested.
Outside is the number of pre-filtered particles to be tested.

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