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Title of Study: Carbon Dioxide (CO_2) Clearance from various face masks in Normal Volunteers when Using a Non-Invasive Positive Pressure Ventilation (NIPPV)

Sponsor: ***Department of Respiratory Care***

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the investigator or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you are a healthy subject. This study is aimed to enroll healthy subjects.

What is the purpose of this study?

The purpose of this study is to determine the level of air pressure required to ensure proper ventilation (wash out of carbon dioxide) provided by a well-fitted mask to your face. The study will use 4 types (2 oronasal and 2 full face) of masks. Also, researcher will ask you to grade each masks'comfort. The study will use a respirator with hose connected to the mask. Carbon dioxide will be collected by tube placed at your nose for measurement. All devices [CapnostreamTM 20p monitor (Medtronic, Minneapolis, MN), ICU ventilator Puritan Bennett™ (Medtronic, Dublin, Ireland) are U.S. Food and Drug (FDA) approved.

How many study subjects are expected to take part in the study?

We will enroll 20 subjects at Rush University.

What will you be asked to do?

If you accept to participate in this study, the researcher will give you an informed consent form to sign. You need to sign the informed consent form before any study-related procedures are performed.

Once consent is signed, the following will be performed:
Vital signs (heart rate, respiratory rate, oxygen saturation, blood pressure) will be collected. Step one, Mask 1 will be randomly chosen out of the 4 masks. Step two, mask will be fitted to face and connected to a noninvasive ventilator. Step three, you will be asked to grade comfort on scale of 1 to 5. Step four, researcher will use three different baseline levels of pressure and (for total of 15 minutes. Vital signs and carbon dioxide level will be monitored and recorded. Step five, you will have a five minutes rest. Step six, researcher will randomly choose mask 2 and repeat steps (3-6). Step seven, researcher will randomly choose mask 3 and repeat steps (3-7) until all 4 masks are tried.

How long will you be in the study?

Duration of study participation is expected to be 2.5 - 3 hours.

You may be removed from this study without your consent. Possible reason may be that the study is canceled.

What are the possible risks of the study?

Possible risks associated with pressurized air via mask are:

- Facial discomfort: it could be due to air leaking between mask and skin or too tight fitting. Researcher will adjust the straps on the mask to minimize these possible risk.
- Vomiting: eating or drinking large amount prior to the study can increase risk for vomiting. To minimize this risk, participants are requested to refrain from moderate to heavy meals/drinks 1 hour before the study.

Are there any anticipated pregnancy risks?

Women

If you are pregnant or breastfeeding, you cannot take part in this study

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study**.**

What other options are there?

The only alternative to participating in this study is not to participate.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. Only de-identified data will be used for data analysis.

If you withdraw from this study, the data already collected from may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

A description of this study will be available on http://www.CLINICALTRIALS.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at anytime.

What are the costs of your participation in this study?

There is no cost to you.

Will you be compensated or paid?

Participates will receive $10 for completing the first hour of the study. They will receive an additional $15 dollars after completing the remainder of the study time.

What happens if you experience a research related injury?

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: David L. Vines Associate Professor, Department of Cardiopulmonary Sciences, Division of Respiratory Care, College of Health Sciences, Rush University. Program Director, Respiratory Care. Tel: 312-942-4408 or Ahmed Al Hussain Graduate student, Respiratory Care, College of Health Sciences, Rush University.

Tel: 312-942-4408. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the. I further attest that all questions asked by the subject or the subject's legal representative were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject or the subject's legally authorized representative and the person signing the form has done so voluntarily.

Signature of Witness/Translator	Date of Signature

☐ Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR
I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.