

Effect of the adjunction of the Double Trunk Mask above standard
nasal cannula during acute hypoxia
5 March 2018

Informed Consent

Epicura ICU Hornu
**Effect of the adjunction of the Double Trunk Mask above standard nasal cannula
during acute hypoxia**

Informed Consent form for patient.

This Informed Consent Form is for men and women who attend clinic Epicura Hornu and who we are inviting to participate in research on adjunctive system to increase oxygenation.

The title of our research project is:

“Effect of the adjunction of the Double Trunk Mask above standard nasal cannula during acute hypoxia”

You may provide the following information either as a running paragraph or under headings as shown below.

Name of Principal Investigator Duprez Frédéric

[Name of Organization: Condorcet Epicura

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Frédéric Duprez, working for the Epicura ICU. We are doing research on hypoxia, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

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There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study (doctor or the staff.)

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Purpose of the research

Hypoxia is one of the most common symptom in ICU. Oxygen therapy at low flow through nasal cannula is used to fight hypoxia. However, this device is not always effective because, in some cases of dyspnea, the higher inspiratory flow introduces air room in your airways, which will decrease fraction delivered in oxygen. Double trunk mask (DTM) is a mask of our conception. The trunks are an oxygen reservoir which fills up oxygen during expiratory phase. The reason we are doing this research is to compare DTM with classical oxygenation through standard nasal cannula.

Type of Research Intervention

This research will involve a blood sample through arterial catheter. However, blood sample is painless.

Participant selection

We are inviting all adults with acute hypoxia attend clinic Epicura to participate in the research on the double trunk mask

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will offer the treatment that is routinely offered in this clinic/hospital for hypoxia, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Procedures and Protocol

In first times, participants in one group will be given the classical treatment with HFO while participants in the other group will be given the same treatment but with a special mask (Double Trunk Mask) which will be located above nasal cannula. After a wash out period, we exchange the treatment between two groups.

This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the treatment is doing, we will find out which treatment you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers

For any clinical study (if relevant):

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We will take arterial blood from your arm using a syringe through arterial line. This blood taken is painless. In total, we will take about 5 samples of 1 ml arterial blood. At the end of the research any left-over blood sample will be destroyed.

B. Description of the Process

- In the first time, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe through arterial catheter. This blood will be tested with a blood analyzer.
- We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.

Duration

The research takes place over two hours

Risks

Any risk can appear during the process. The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the treatment is doing, we will find out which treatment you are getting and make changes.

Benefits

If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

Reimbursements

Your participation is free. You will not be given any other money or gifts to take part in this research

Confidentiality

With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [Duprez Frédéric and Bruyneel Arnaud] who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

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Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the centre/institute/hospital.

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [Dr Mashayekhi Sharam Chief of ICU 003265/71.36.44)

This proposal has been reviewed and approved by [Comité Ethique Erasmes], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand...." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

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Print Name of Participant _____

Signature of Participant _____

Date _____
Day/month/year

If illiterate

Aliterate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness _____

AND Thumb print of participant

Signature of witness _____

Date _____
Day/month/year



Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

- 1.**
- 2.**
- 3.**

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____
Day/month/year

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