Information for participation in medical scientific research

Representative information

CONFIDENCE – A comparison between methods of deresuscitation

'Effect of lung ultrasound guided fluid deresuscitation on duration of ventilation in Intensive Care Unit patients'

Introduction

Dear Sir/Madam,

We would like to ask for your permission on behalf of the person you are currently legally representing for her/his participation in a clinical study that **compares the effects of two strategies of deresuscitation on the duration of invasive ventilation** in Intensive Care Unit (ICU) patients. Due to the necessity to start deresuscitation as soon as possible when the patient is hemodynamically stable, randomization (drawing) between two different strategies of deresuscitation was performed directly after start of ventilation. The person you represent is being deresuscitated according to this method.

Before you decide whether you give permission for continuation of this study, we will explain what this study entails and what it means for the person you represent. **Please read this information thoroughly and ask the investigator for an explanation if you have any questions.** You can consult with your friends or family. It is also possible to consult an independent expert, mentioned at the end of this letter, for additional information. Further information about participating in a study can be found on the website of the Central Government: https://www.government.nl/topics/medical-research.

1. General information

This study is designed by the ICU of the Amsterdam Medical Center (AMC), and is subsidized by the Dutch organization for health-research and care innovation (ZonMw). This study is being conducted in several hospitals in the Netherlands. A total of 1000 patients is needed for reliable results of the study.

The Medical Research Ethics Committee AMC has approved this study. General information about medical research can be also found on the website of the Central Government: www.rijksoverheid.nl/mensenonderzoek.

2. Aim of the study

The aim of this study is to find out **whether the duration of invasive ventilation is shortened by lung ultrasound guided deresuscitation.**

3. Background of the study

When a patient is admitted to the ICU, fluid administration (resuscitation) is often needed to raise blood pressure. In addition, invasive ventilation is often necessary because of lung failure or other serious illness.
Fluid overload is a negative consequence of fluid administration and often leads to lung edema. Untimely recognition of lung edema can lead to prolonged duration of invasive ventilation in ICU patients. Lung ultrasound is a simple, safe and non-invasive bedside imaging tool that can accurately detect lung edema. Lung edema is treated with diuretics, also called water pills. Diuretics work by acting on the kidneys to increase the production of urine. This is called **deresuscitation.**

In this study, we will investigate whether detection of lung edema with the use of lung ultrasound can be used to improve and accelerate deresuscitation treatment. This way, we hope to shorten duration of invasive ventilation. Lung ultrasound scores will be collected, as well as other (clinical) data.

4. What participation involves

In this study, two strategies of deresuscitation are compared. Half of the participants are deresuscitated without lung ultrasound guiding (standard care); the other half of the participants are deresuscitated with lung ultrasound guiding (intervention). We randomly assign patients to one of these two strategies.

Due to the necessity to start deresuscitation as soon as possible when the patient is hemodynamically stable, **randomization (drawing)** between two different strategies of deresuscitation was performed directly after start of ventilation. No other actions are performed and no other treatments given.
The following actions are performed in this study:

A. **Intervention group: lung ultrasound twice a day.** Lung ultrasound is a non-invasive instrument that looks at the amount of edema (fluid overload) in the lungs and is performed in about five minutes. Lung ultrasound uses ultrasound waves to form an image and is without side effects. It is in addition to standard care.

Or

B. **Control group (standard care): no extra actions or treatment.** Standard care is given during deresuscitation.

Due to the acute circumstances and the necessity to start deresuscitation as quickly as possible, consent of the person you are legally representing cannot be obtained. Therefore, we ask for your consent on his or her behalf to participate in this study. The Medical Research Ethics Committee AMC has granted permission for the use of deferred consent.

Participation in this study means that, during the period that the patient is admitted to the ICU, medical data that is important for the examination is collected from the patient's record (medical history, physical examination and chest radiographs). Furthermore, we collect ventilation data from the ventilator daily. As a part of the study, we will approach the person you represent four weeks after inclusion in this study, for a short questionnaire regarding his/her overall functioning and quality of life. After three months, we will contact him/her once more to ask how he/she is doing.
When the person you represent is awake and adequate, we will inform him/her about the study and we will ask again for consent to use the already collected data. If the person you represent does not agree with your decision for participation in this study, all collected data will be discarded.

5. What are we asking permission for?

We ask your consent for continuation of participation of the person you represent in this study and for continuation of collection of data. All data will be processed anonymously (see chapter "What happens with the data"). The person you represent has been assigned to one of the two strategies of deresuscitation since the start of ventilation. If you give consent, then the deresuscitation strategy will be continued as is. If you do not give consent, then participation will stop and any data collected up to this point will be discarded. If you give consent for continuation of the study, we kindly ask you to sign the consent form.

6. What is expected of you?

It is important that you contact the researcher:

- if you no longer give consent for the participation of the person you represent in the study
- if your contact information changes

7. Possible risks and discomforts

Use of lung ultrasound is **without risks** and is already being used on a regular basis in daily practice.

8. Possible advantages and disadvantages

Participation in this study could give the patient an advantage. It is possible that the duration of ventilation will be shortened when the patient is assigned to the group of lung ultrasound guided deresuscitation. A disadvantage of participation in this study could be a low blood pressure, but this is monitored continuously and will be treated directly by the physician if necessary. On rare occasions, important new medical information is found coincidentally during performance of lung ultrasound. In this case, the patient's representative will be informed by the physician.

Participation in this study will contribute to knowledge of optimal treatment of invasively ventilated ICU patients and is therefore of great importance for **future patients** in need of invasive ventilation and deresuscitation. This study may also reduce the use of invasive methods for measurements.

9. If you want to stop the participation in the study

It is up to you to decide whether the study is continued for the person you represent. Participation is voluntary. If you decide you would rather not give consent for the continuation of this study on behalf of the person you represent, there are no consequences for the treatment he/she is receiving. You may also decide to withdraw your consent at any time during the study. The collected medical data will not be used. You do not have to clarify why you don't want the patient to continue in this study. It is also possible to destroy data that was already collected.

10. End of the study

The participation in the study of the person you represent stops when

- all measurements are collected;
- you decide that the collected data cannot be used;
- the researcher or treating physician finds it better to stop;
- the ICU of the Amsterdam UMC, location AMC or the government or Medical Research Ethics Committee decides to stop the study;
- after the patient has received a phone call after 28 and 90 days, in which we ask his/her (physical) health.

The study is concluded once all the participants have completed the study.

11. Use and storage of the data

Which data will be stored and why?

For this study, it is necessary to collect, use and store **medical and personal data** of the patient. These include data such as his/her date of birth and data about his/her health. The collection, use and storage of the data is necessary to be able to answer the questions posed in this study and to be able to publish the results.

How do we protect privacy?

All of the data will remain **confidential** and will receive a code to protect her/his privacy. His/her name and other data that can directly identify him/her are omitted. Data can only be traced back to him/her with the key to the **code.** The key to the code will stay with the investigator, securely stored in the local research institution. In the reports about the study, only this code will be used. In reports that will be shared with the sponsor of this study, no names and other data will be used, only codes. In publications and articles, data can not be traced back to the person you represent.

Who can access the data

A selected group of people can access all of the data at the research location. This is necessary to monitor whether conduction of the study is **reliable**. People who may access the data are: the principal investigator, research coordinators, Healthcare Inspectorate (IGZ) and the representative who has been commissioned by the sponsor of the study. They will keep the data secret. If you sign the consent form, you also give permission for this inspection.

How long will the data be saved?

The researcher will save data for 15 years at the research institution.

Will the stored data be used in other research?

The data of the person that you represent may still be of interest after the end of this study for other clinical research regarding invasive ventilation. When the patient you represent is able to give consent, we will ask for his/her permission. If he/she does not consent, the data will be used for this study only.

Can you withdraw consent to use the data?

You can always withdraw your consent for the use of the personal data of the person you represent. This applies to this study and also to the storage and use of data for future research. The study data that has been collected until the time you withdraw your consent will be destroyed.

Would you like to receive more information about privacy?

For general information about rights concerning the processing of personal data, please consult the website of the Dutch Data Protection Authority (Dutch translation: Autoriteit Persoonsgegevens).
If you have any questions about rights, please contact the organization responsible for processing the data of the person you represent. For this study it is AMC. See appendix A for contact information.

If you have are any questions or complaints regarding the data processing procedure, we recommend that you contact the study site. You can also contact the Data Protection Officer of the AMC of the Dutch Data Protection Authority.

Where can you find more information about the study?
Information about this research is also included in an summary of medical research i.e. www.clinicaltrials.gov. This does not include any data that can be traced back to the person you represent. After the study, the website may contain a summary of the results of this study. You can find this study under 'CONFIDENCE'.

12. Insurance for human subjects

As this study adds no additional risks by participating in this study, the Medical Research Ethics Committee has granted exemption from the obligation to take out additional insurance.

13. Informing the treating physician

We informed the treating specialist of the person you represent from the ICU about the participation in this study. The participation is noted in her/his electronic patient file. We will not inform her/his general practitioner about the participation in this study.

14. No compensation for participation

Participation in this study is completely voluntary and does not lead to additional costs. You will not receive a reimbursement for participating in this study.

15. Any questions?

If you have any questions, you can contact the intensivist on duty (possibly via the nurse).
You may contact the independent physician for advice about participating in this study.
He/she is informed about the research, but is not the coordinator of this study.
If you have complaints about the study, you can discuss it with the researcher or the physician treating the person you represent. If you prefer not to do this, you can contact the complaints committee of the hospital the person you represent is admitted to. All information can be found in **Appendix A: Contact details.**

16. Signing the consent form

When you have had sufficient time for deliberation, you will be asked to decide on participation of the person you represent in this study. If you give permission, we ask you to confirm this by signing the **permission statement**. Your signature confirms that you have understood the information and agree to participation of the person you represent in the study. The signature sheet is kept by the treating physician. You will receive a copy of this consent form.

Thank you for your attention.

17. Appendices to this information

A. Contact details for Amsterdam UMC location AMC
B. Consent form for the legal representative

Appendix A: contact details for Amsterdam UMC, location AMC

Researchers

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Meibergdreef 9, 1105 AZ Amsterdam
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In case of complaints

Complaints Officer Amsterdam UMC, location AMC
Phone number: 020-566 3355
Available on workdays, 9:00-15:30

Chief information security and privacy protection Amsterdam UMC, location AMC: fg@amc.nl
For more information about your rights and the person you represent: fg@amc.nl

Appendix B: consent form for the patient

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- I have read and understand the information form. I have had the opportunity to ask questions, which have been answered to my satisfaction. I have had enough time to decide if the person I represent participates in this study.
- I have the right to withdraw my consent at any time without the need to provide an explanation and without effect on the medical treatment of the person I represent.
- I am aware that a selected group of people can access the data of the person I represent. These people are listed in this information letter.
- I give permission to contact the person I represent on the 28th day, in case he/she is no longer admitted to the Intensive Care Unit, and on the 90th day after the start of ventilation.
- I consent to collected data for this research being used in the way and for the purpose stated in the information letter.

I give permission to participation in the trial of the person mentioned above.

Surname and initials legal representative:
Relation to the patient:

Signature: …… Date : __ / __ / __

Signatory declares that the person mentioned above is fully informed about this study.

If information comes to light during the course of the study that could affect the patient's consent, I will inform him/her in a timely fashion.

Name of investigator/doctor (or his/her representative):…….
Signature:…… Date: __ / __ / __

The representative of the human subject will receive a full information letter, together with a signed version of the consent form