Information for participation in medical scientific research

Patient 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,

Your representative granted permission for your participation in a clinical study that **compares the effects of two strategies of deresuscitation on 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) was performed between two different strategies of deresuscitation. You were subsequently deresuscitated according to this method.
We would like to ask for your permission to use the data that we have already collected while you were ventilated. In this letter we will explain what this study entails and what you sign up for if you give permission to use the data collected for this study.

Please read this information carefully and ask the investigator for an explanation if you have any questions. You can consult with your partner, 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 another 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 (for example no X-rays, no contrast dye and no catheter placement) 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 guided with lung ultrasound guiding. We randomly assign patients to one of these two strategies.

Due to the acute circumstances and the necessity to start ventilation as quickly as possible, your consent could not be obtained. Therefore, deferred consent for your participation was obtained from a representative on your behalf. The Medical Research Ethics Committee AMC granted permission for the use of deferred consent.

Participation in this study means you were **randomly assigned** to a deresuscitation strategy: with or without the guidance of lung ultrasound. No other actions were performed and no other treatments were given.
The following actions were performed in this study:

A. **Intervention group: lung ultrasound twice a day** during your stay at the ICU with a maximum of 28 days. 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 routine care.

Or

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

Participation in this study means that during the period you were admitted to the ICU, medical data that is important for the examination was recorded from your medical record (medical history, physical examination and chest radiographs). Furthermore, we collected ventilation data from the ventilator daily. As a part of the study, we will approach you four weeks after inclusion in this study, for a short questionnaire regarding your overall functioning and quality of life. After three months, we will contact you once more to ask how you are doing.

5. What are we asking permission for?

We ask your consent to use the data that we have already collected while you were invasively ventilated. All data will be processed anonymously (see chapter "What happens to your data?"). If you do not give your consent, then the collected data will be discarded. If you give your consent to use the already collected data for this study, we kindly ask you to sign the consent form. We also ask permission to contact you twice after inclusion in this study (on day 28 and 90).

6. What is expected of you?

It is important that you contact the researcher:

- if you no longer want to participate 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 means that you could have had an advantage. It is possible that your duration of ventilation was shortened, when assigned to the group of lung ultrasound guided deresuscitation. A disadvantage of participation in this study could have been a low blood pressure, but this was monitored continuously and directly treated by the physician if necessary. On rare occasions, important new medical information is found coincidentally during performance of lung ultrasound. In this case, you 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 don’t want the collected data to be used

It is up to you to decide whether we can use the already collected data for scientific research. If you decide you would rather not consent to the use of the collected data for scientific research, there are no consequences for the treatment you receive as a patient. The collected medical data

will not be used. You do not have to clarify why you do not want the collected data to be used. It is also possible to destroy data that was already collected.

10. End of the study

Your participation in the study 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, the government or the Medical Research Ethics Committee decides to terminate the study;
- after you received a phone call after 28 and 90 days, in which we ask about your (physical) health.

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

11. What happens after this study?

If you are interested in the results of this study, you can mention this. After all the records are collected, the researcher will inform you about the most important results of the study. It is not possible to predict how long it will take to collect all the data to inform you. By then, the researcher can also inform you which group you were assigned to. If you prefer not to be informed about the results of the study, you can inform the researcher and he or she will not tell you.

12. What happens with your data?

Which data will be stored and why?

For this study, it is necessary to collect and use your **medical and personal data.** These include data such as your date of birth and data about your health. The collection, use and storage of your data is necessary to be able to answer the questions posed in this study and to publish the results. It is also possible to give permission to use stored data for future research.

How do we protect your privacy?

All your data will remain **confidential** and you will receive a code to protect your privacy. Your name and other data that can directly identify you are omitted. Data can only be traced back to you 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, your data can not be traced back to you.

Who can access your data?

A selected group of people can access all of your 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 your data be saved?

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

Can the stored data be used in other studies?

Your data may still be of interest after the end of the study for other clinical research regarding invasive ventilation. You can indicate on the consent form if you do or do not agree with this. If you do not consent to this, the data will be used for this study only.

Can you withdraw your consent to use your data?

You can always withdraw your consent for the use of your personal data. This applies to this study and also to the storage and the 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 your privacy?

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

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

Where can you find more information about the study?

Information about this study is also included in a summary of medical research i.e. www.clinicaltrials.gov. No data that can be traced back to you is included. After the study, the website may contain a summary of the results of this study. You can find this study under 'CONFIDENCE'.

13. 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.

14. Informing the treating physician

We informed your treating specialist from the ICU about your participation in this study. Your participation is noted in your electronic patient file. We will not inform your general practitioner about the participation in this study.

15. No compensation for participation

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

16. 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 your treating physician. If you prefer not to do this, you can contact the complaints committee of your hospital.
All information can be found in **Appendix A: Contact details.**

17. Signing the consent form

When you have had sufficient time for deliberation, you will be asked to decide whether we may use your collected data for scientific research. 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 the use of collected data for research. The signature sheet is kept by your treating physician. You will receive a copy of this consent form.

Thank you for your attention.

18. Appendices to this information

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

Appendix A: contact details for Amsterdam UMC, location AMC

Researchers
Drs. S.G. Blok
Intensive Care Unit
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Meibergdreef 9, 1105 AZ Amsterdam
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Dr. F. Paulus
Intensive Care Unit
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Independent Physician
Prof. Dr. J. Horn
Amsterdam UMC, locatie AMC
Meibergdreef 9, 1105 AZ Amsterdam
E-mail: j.horn@amsterdamumc.nl

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: fg@amc.nl

Appendix B: consent form for the patient

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

- 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 whether the collected data for this study can be used.
- I have the right to withdraw my consent to use my data for this study, until the moment my data has been published, without having to provide an explanation. I have the right to withdraw my consent to use my data for future research at any time.
- I am aware that a selected group of people can access my data. These people are listed in this information letter.
- I agree to be contacted on the 28th day, in case I am no longer admitted to the Intensive Care Unit, and on the 90th day after the start of ventilation.
- I consent to my data collected for this research being used in the way and for the purpose stated in the information letter.

Please fill in the table below with yes or no.

I give permission to the storage and use of my personal data for future research.	Yes ☐	No ☐
I give permission to approach me again after this investigation for a follow-up investigation.	Yes ☐	No ☐
I want to be informed about which group I have been assigned to.	Yes ☐	No ☐

I want to participate in this study.

Surname and initials: ……..

Signature: …… Date : __ / __ / __

---------- I declare that I have fully informed the patient about the aforementioned research..

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