Information for participation in medical scientific research

PEGASUS – Personalized ventilation versus standard ventilation

Official title: Personalized Mechanical Ventilation Guided by UltraSound in Patients with Acute Respiratory Distress Syndrome.

Introduction

Dear Sir/Madam,

Your legal representative granted permission for your participation in a clinical study that compares personalized ventilation with standard ventilation in patients with acute lung injury. Immediately after the diagnosis acute lung injury, randomization (drawing) was performed between the two different ventilation strategies. You were ventilated according to the drawn 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 meant for you and what you sign up for if you give permission.

Please read this information carefully and ask the investigator for an explanation if you have any questions. Besides consulting with your partner, friends or family it is also possible to consult an independent expert, who is 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 Intensive Care (IC) of Amsterdam UMC, location AMC, and is subsidized by the Amsterdam UMC. This international study is being conducted in several hospitals inside and outside the European Union. A total of 538 patients is needed for reliable results of the study. The institutional review board of the AMC has approved this study.

2. What is the purpose of the study?

The aim of this study is to compare personalized ventilation with standard ventilation in patients with acute lung injury, also known as Acute Respiratory Distress Syndrome (ARDS). With this study, we hope to find out whether personalized ventilation reduces the chance for the patient to decease in comparison to standard ventilation.

3. What is the background of the study?

Patients who develop acute lung injury often have low levels of oxygen in their blood. When the oxygen levels become too low, mechanical ventilation can be necessary and lifesaving. However, ventilation can also be harmful to the lungs. At the moment, all patients with acute

lung injury receive the same ventilation strategy. In this study we distinguish between patients with focal (concentrated in a part of the lung) or non-focal (distributed throughout the lung) acute lung injury. We can assess the type of acute lung injury with ultrasound, a simple, non-invasive and safe form of imaging which is well tolerated by patients and can be performed at the bedside. The ventilation will be adjusted based on the type of acute lung injury (focal or non-focal).

4. What participation involves

In order to compare both ventilation strategies with each other, half of the patients are ventilated with standard ventilation and the other half are ventilated with personalized ventilation. After the diagnosis of acute lung injury, a lung ultrasound was performed to determine whether you had focal or non-focal acute lung injury and you were randomly assigned to one of the two ventilation strategies;

Group 1. The patients in this group receive a personalized ventilation strategy;

- With focal acute lung injury, patients are ventilated with lower ventilation pressures in combination with prone position to protect the healthy parts of the lungs as much as possible.
- With non-focal acute lung injury, patients are ventilated with higher pressures to provide the entire diseased lung with air and oxygen.

Group 2. The patients in this group receive standard ventilation. The ventilation is set by the intensivist and is based on current evidence.

Participation in this study meant that during the period of time that you were admitted to the ICU, medical data was stored from your medical record (medical data, lung ultrasound examination). Furthermore, we collected ventilation data from the ventilator daily.

Due to the importance to apply the correct ventilation strategy as soon as possible, this study was started immediately after the diagnosis of acute lung injury. Due to the acute situation, your permission could not be obtained before the start of the study. Therefore, deferred consent for you participation was obtained from a representative on your behalf after the start of this study. The institutional review board of the AMC granted permission for the use of deferred consent.

5. What are we asking permission for?

We ask for your consent to use the data that we collected while you were invasively ventilated. All data will be processed confidentially (see chapter "What happens to your data?"). If you do not give your consent, the collected medical data will not be used and destroyed. You do not have to clarify why you do not want the collected data to be used. If you give your consent to use the collected data for this 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 want to participate in the study
- If your contact information changes

7. Possible risks or discomforts

Participation in this study probably did not increased the risk of complications because all of the ventilation methods in this study are already being used in the current practice. The physician could change the ventilation strategy if deemed necessary. For this study, you were not ventilated any longer than necessary and there were no other changes in the care that you received.

An additional lung ultrasound was required for the study. Lung ultrasound is an examination which is often used in intensive care. It gives no extra radiation and is well tolerated by patients.

8. Possible advantages and disadvantages

It is important that you carefully consider the possible advantages and disadvantages before you decide to participate in this study. A possible advantage is that personalized ventilation based on the type of acute lung injury may be less harmful than standard mechanical ventilation and leads to less lung injury, but this has not been proven. No disadvantages are expected when participating in this study. There are no additional hospital visits required for this study.

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 and will be destroyed. You do not have to clarify why you do not want the collected data to be used.

10. When does the study end?

In these situations, the study will stop for you:

- The continued observation period, 90th day after the start of the study, has passed. If you are discharged from hospital within this period, we only want to know where you are at the 90th day (at home or in a different hospital). We can often get this information out of your patient file.
- You decide that the collected data cannot be used.
- The research team or your physician finds it better to stop.
- The ICU of the Amsterdam UMC, location AMC or the government or the institutional review board decides to stop the study.

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

11. What happens after the study has ended?

If you are interested in the results of this study, you can mention this. It is not possible to predict how long it will take until the study results can be shared with you. If you want, the researcher can also inform you in which group you were assigned to.

12. What will be done with your data?

Which data will be stored and why?
For this study, it is necessary to collect and store both 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?
To protect your privacy, we give a code to your data. We only put this code on your data. We keep the key to the code in a safe place in the hospital. When we process your data, we always use only that code. Your data can be shared with participating hospitals, this will be done by only using that code. Even in reports and publications about the study, nobody will be able to see that it was about you.

Who can see your data?
Some people can see your name and other personal information without a code. These are people checking whether the investigators are carrying out the study properly and reliably. These persons can access your data:

- Members of the committee that keeps an eye on the safety of the study.
- National and international supervisory authorities. For example, the Healthcare and Youth Inspectorate.

These people will keep your information confidential. We ask you to give permission for this access.

Can we use your data for other research?
Your data may also be important after this study for other medical research on acute lung injury. For this purpose, your will be stored the hospital for 15 years. Please indicate in the consent form whether you agree with this. Do you not want to give your consent for using the data for other research? Then you can still take part in this study. You will get the same healthcare.

Can you retract your consent for the use of your data?
You can retract your consent for the use of your data at any time. This applies both to the use in this study and to the use in other medical research. But please note: if you retract your consent, and the investigators have already collected data for this research, they are still allowed to use this information.

We will send your data to countries outside the European Union
In this study, we will send your coded data to countries outside the European Union. The privacy rules of the European Union do not apply in those countries. But your privacy will be protected on an equal level.

Do you want to know more about your privacy?

- Do you want to know more about your rights when processing personal data? Visit www.autoriteitpersoonsgegevens.nl.
- Do you have questions about your rights? Or do you have a complaint about the processing of your personal data? Please contact the person who is responsible for processing your personal data. For the present study, this is:
    - The AMC. See Appendix A for contact details, and website.
- If you have any complaints about the processing of your personal data, we recommend that you first discuss them with the research team. You can also contact the Data Protection Officer of the AMC. Or you can submit a complaint to the Dutch Data Protection Authority.

Where can you find more information about the study?
You can find more information about the study on the following website, www.ClinicalTrials.gov. After the study is completed, the website may show a summary of the results of this study. You can find the study by searching for PEGASUS.

13. Will you receive compensation if you participate in the study?

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

14. Are you insured during the study?

Insurance has been taken out for everyone who takes part in this study. The insurance pays for damage caused by the study. But not for all damage. You can find more information about this insurance and any exceptions in Appendix B. It also says who you can report damage to.

15. We informed your 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.

16. Do you have any questions?

You can ask questions about the study to the research team or the intensivist on duty. Would you like to get advice from someone who is independent from the study? Then contact the independent physician. She knows a lot about the study, but is not a part of this study.
Do you have a complaint? Discuss it with the investigator or the physician who is treating you. If you prefer not to do so, please visit the complaints committee of the hospital. Contact information can be found in Appendix A.

17. How do you give consent for the study?

You can first think carefully about this study. Then you tell the investigator if you understand the information and if you want to take part or not. If you want to take part, fill in the consent form that you can find with this information sheet. The signature sheet is kept within the research team. You will receive a copy of this consent form.

Thank you for your attention and time.

– Appendices to this information

A. Contact details
B. Insurance information
C. Consent form

Appendix A: Contact details for AMC

Investigator

Dr. L.D.J. Bos, senior investigator
Intensive Care
An appointment can be made via the secretariat of the ICU;
E-mail: div6-ic-secretariaat@amsterdamumc.nl
Telephone number: +31 (0) 20 566 2509

Independent doctor

Prof. dr. J. Horn, intensivist
Intensive Care
An appointment can be made via the secretariat of the ICU;
E-mail: div6-ic-secretariaat@amsterdamumc.nl
Telephone number: +31 (0) 20 566 2509

Complaints

Klachtenfunctionaris AMC
020-566 3355
Available on working days, 9:00-15:30

Data Protection Officer of the AMC: privacy@amsterdamumc.nl
For more information about your rights: privacy@amsterdamumc.nl

Appendix B: INSURANCE INFORMATION

The AMC has taken out insurance for everyone participating in this study. The insurance covers damage caused by participating in the study. This applies to damage during the investigation or within four years of the end of the study period. You must have reported damage to the insurer within those four years.

The insurance does not cover all damage. At the bottom of this text is a brief description of which damage is not covered.
These provisions are contained in the 'Besluit verplichte verzekering bij medisch-wetenschappelijk onderzoek met mensen'. This decision can be found on www.ccmo.nl, the website of the Centrale Commissie Mensgebonden Onderzoek (see 'Library' and then 'Laws and regulations').

In the event of damage, you can contact the insurer directly.

The insurance company of this study is:	
Name Insurer:	Centramed B.A.
Address Insurer:	Postbus 7374 2701 AJ Zoetermeer
Phone number:	070 301 70 70
E-mail:	info@centramed.nl
Polisnumber:	624.528.303

The insurance offers cover of € 650,000 per test subject with a maximum of € 5,000,000 for the entire research and € 7,500,000 for damage as a result of medical scientific research reported per insurance year.

The insurance does **not** cover the following damage:

- damage from a risk of which you have been informed in the written information. This does not apply if the risk is more serious than anticipated or if the risk was very unlikely;
- damage to your health that would also have occurred if you had not taken part in the study;
- damage caused by not (fully) following directions or instructions;
- damage to your descendants, as a result of a negative effect of the research on you or your descendants;
- damage caused by an existing treatment method in research into existing treatment methods.

Furthermore, the subject is requested to contact Dr. L.D.J. Bos, +31 (0) 20 566 2509.

Appendix C: Informed consent form patient

Belonging to the PEGASUS study.

- I have read the information sheet. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I wanted to take part.
- I know that taking part is voluntary. I also know that at any time I can decide not to take part in the study. Or to stop taking part. I do not have to explain why.
- I give consent to collect and use my data. The investigators only do this to answer the question of this study.
- I give the researchers permission that the coded data may be shared with participating hospitals.
- I know that some people will be able to see all of my data to review the study. These people are mentioned in this information sheet. I give consent to let them see my data for this review.
- □ **I give**

  □ **I don't give**

  permission to use my personal data for future research in the field of ventilation.
- □ **I give**

  □ **I don't give**

  permission to approach me again after this investigation for a follow-up investigation.
- □ **I want**

  □ **I don't want**

  to be informed about which group I have been assigned to.
- I want to take part in this study.

My name is (patient): ……..

Signature: …… Date: __/__/__

I declare that I have fully informed this person about the study mentioned.
If any information becomes known during the study that could influence the person's consent, I will let this person know in as soon as possible.

Investigator name (or their representative): .....

Signature:…… Date: __/__/__

The patient will receive a complete information sheet, together with a signed version of the consent form.