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,

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 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. The person you represent is currently being ventilated according to the drawn 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 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 the person you represent had focal or non-focal acute lung injury and was randomly assigned to one of the two ventilation strategies;

Group 1. The patients in this group are ventilated with a personalized ventilation strategy, depending on the type of acute lung injury (focal or non-focal);

- 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 ventilator is set by the intensivist and is based on current evidence.

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, lung ultrasound examination). Furthermore, we collect ventilation data from the ventilator daily.

Due to the necessity to immediately apply the correct ventilation strategy to the person you represent, the study was started directly after the diagnosis of acute lung injury. Due to the acute situation, consent of the person you are legally representing could not be obtained before the start of the study. Therefore, we ask for your consent on his or her behalf to continue the study. The institutional review board of the AMC has granted permission for the use of deferred consent.

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 confidentially (see chapter "What happens with the data"). The person you represent has been assigned to one of the two ventilation strategies since the diagnosis of acute lung injury. If you give consent, then the ventilation 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

Participation in this study probably does not have additional risks of complications because all ventilation methods investigated in this study are already being used in practice. If deemed necessary, the physician can change the ventilation strategy at any moment. For this study, the person you represent will not be ventilated any longer than necessary and there are no other changes in the care that he/she will receive.
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 if the person you represent will 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 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 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. The collected medical data will not be used. You may also decide to withdraw your consent at any time during the study. You do not have to clarify why you don’t want to continue in this study. In the latter case, the researchers will use the data collected up to the moment of stopping.

10. When does the study end?

In these situations, the study will stop for the person you represent:

- The continued observation period, 90th day after the start of the study, has passed. If the person you represent is discharged from the hospital within this period, we only want to know where he/she is on the last day of this study (at home or in a different hospital). We can often get this information out of the patient file.
- When you have decided not to give consent or to withdraw your consent.
- The research team or the 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 the person you represent is assigned to.

12. What will be done with the data of the person you represent?

What data do we store and why?

For this study, it is necessary to collect, use and store both medical and personal data of the person you represent. These include data such as date of birth and data about 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 the privacy of the person you represent?

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. Data can be shared with participating hospitals, this will be done by only using that code. 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 cannot be traced back to the person you represent.

Who can see the data?

A selected group of people can access all of the data at the research location. These are people checking whether the investigators are carrying out the study properly and reliably. These persons can access the 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 the information confidential. We ask you to give permission for this access.

Can we use the data of the person you represent for other research?
The data of the person you represent may also be important after this study for other medical research on acute lung injury. For this purpose, the data 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 the person you represent can still take part in this study. He/she will get the same healthcare.

Can you retract your consent for the use of the data?
You can retract your consent for the use of the data of the person you represent 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 research, they are still allowed to use this information.

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

Do you want to know more about privacy?

- Do you want to know more about the rights of the person you represent 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 the data of the person you represent? Please contact the person who is responsible for processing the 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 the personal data of the person you represent, 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 the person you represent receive compensation for participation in the study?

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

14. Is the person you represent 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 will inform the treating physician

We informed the treating specialist from the ICU about the participation of the person you represent in this study. The participation is also noted in the 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 physician treating the person you represent. If you prefer not to do so, please visit complaints committee of the hospital.
Contact information can be found in Appendix A.

17. How do you give consent for the study?

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 consent form. Your signature confirms that you have understood the information and agree to the participation of the person you represent in the study. The signature sheet is kept with the research team. You will receive a copy of this consent form.

Thank you for your attention and time.

16. 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 the health of the person you represent that would also have occurred if he/she had not taken part in the study;
- damage caused by not (fully) following directions or instructions;
- damage to the descendants of the person you represent, as a result of a negative effect of the research on the person you represent or his/her 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 - Representative

Belonging to PEGASUS

I have been asked to give consent for the following person to take part in this medical study:

Patients name: …….. Date of birth: __/__/__

- I have read the information sheet for representatives. I was able to ask questions. My questions have been answered well enough. I had enough time to decide if I want this person to take part.
- I know that taking part is voluntary. I also know that I can decide . I do not have to explain why.
- I give consent to collect and use this persons data. The investigators will 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 this person's data to review the study. These people are mentioned in this information sheet. I give consent to let these people see this person's data for this review.
- □ **I give**
  □ **I don't give**
  permission to use the personal data of the person I represent for future research in the field of ventilation.
- □ **I give**
  □ **I don't give**
  permission to approach the person I represent again after this investigation for a follow-up investigation.
- □ **I want**
  □ **I don't want**

  to be informed about which group the person I represent has been assigned to.
- I agree that this person takes part in this study.

Name of legal representative: .....

Relationship to the subject: ……

Signature: …… Date: __/__/__

I declare that I have fully informed the person(s) mentioned above about the present study.

If any information becomes known during the study that could influence the representative's consent, I will let them know as soon as possible.

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

Signature: …… Date: __/__/__

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