Title:

Low Pressure Pneumoperitoneum and Deep Neuromuscular Block vs. Standard During RARP to Improve Quality of Recovery; a Randomized Controlled Study. (RECOVER-2)

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Participant Information for Participation in Medical-Scientific Research

Information Sheet for Participation in the RECOVER 2 Study
The effect of low-impact laparoscopy versus standard laparoscopy during robot-assisted prostatectomy on recovery quality and the immune system.

Dear Sir,

You are receiving this letter because you are scheduled to undergo a robot-assisted prostatectomy, and your treating physician has informed you about this medical-scientific study. Participation is voluntary. If you wish to participate, a consent form will be completed with you. Before deciding whether or not to participate, we kindly ask you to carefully read the written information and discuss the subject with friends and/or family. General information about participating in such a study is available on the Dutch Government website: www.rijksoverheid.nl/mensenonderzoek.

If you have any questions after reading all the information, you can contact the researcher or an independent doctor, who is knowledgeable about the study but not involved in it.

1. General Information

This study was initiated by physicians at the Radboud University Medical Center and is being conducted at the Canisius Wilhelmina Hospital in Nijmegen. A part of the costs for this study is covered by the pharmaceutical company Merck. A total of 96 participants are needed in the Netherlands for this study. The study complies with internationally established research guidelines and has been approved by the Executive Board of Radboud University Medical Center and Canisius Wilhelmina Hospital, as well as the Medical Ethical Review Committee Arnhem-Nijmegen.

2. Background and Purpose of the Study

Our research group has been studying ways to improve recovery after laparoscopic surgeries (also called minimally invasive surgery) for many years. During such a procedure, the abdomen is inflated to create space for the camera and surgical instruments. Muscle relaxants (such as rocuronium) help create more space and prevent involuntary muscle movements in the patient. In this study, we aim to measure whether lower pressure in the abdomen combined with deep muscle relaxation leads to better recovery, less pain after surgery, and possibly a better functioning immune system.

3. What Participation Involves

If you agree to participate, you will be randomly assigned to one of two groups: one group will have a lower abdominal pressure with deep muscle relaxation, and the other will have normal pressure with standard muscle relaxation. After the surgery, the muscle relaxation will be reversed using a medication called sugammadex. Only at the end of the study will we inform you which group you were in. Whether participating will provide benefits for you cannot be predicted.

The immune system responds to damage in the abdomen, and we will measure if this response differs with lower pressure. During the surgery, a fluorescent contrast fluid (indocyanine green) will be administered to visualize the blood supply to the abdominal wall. A video recording will be made during its administration. Additionally, a small piece (1 x 1 cm) of the abdominal lining (peritoneum) will be removed at the beginning and end of the surgery. This will not cause any problems, as it will be done with a camera, allowing the surgeon to check for any small bleeding, which can be immediately controlled. Blood will be taken before, during, and after the surgery for treatment purposes. Additional blood samples will be taken for the study.

To assess the quality of recovery, we will ask you to complete questionnaires at three time points, as outlined below. Each questionnaire will take 5-10 minutes to complete. Finally, we will ask you to rate any pain and nausea you experience, and we will look up how much medication you needed for these symptoms and when you were discharged.

Summary of what participating in this study means for you:

Before the surgery	2 questionnaires, 3 extra blood samples
During the surgery	2 small pieces of peritoneum, administration of fluorescent contrast fluid.
1 day after surgery	1 questionnaire, 2 extra blood samples.
10-12 days after surgery	2 questionnaires, 3 extra blood samples.
3 months after surgery	2 questionnaires.

The above time points will coincide with your regular care and outpatient visits, meaning you do not need to come to the hospital separately for the study. There are no extra costs for you for this study.

4. Risks

In our experience, operating with lower abdominal pressure and deep muscle relaxation is safe, and other researchers have confirmed this. If the surgeon is unable to see clearly with the lower pressure, the pressure will be increased to the normal level. As with patients who do not participate in the study, there is always a small chance that the surgery may need to be converted to an open procedure (via an abdominal incision). This chance is not increased by using lower pressure or deeper muscle relaxation.

The medication used to reverse muscle relaxation (sugammadex) may have some side effects. For example, for 6 hours after surgery, you should not receive two specific types of antibiotics. Your treating physician is aware of this and can prescribe an alternative if necessary. Sometimes (in fewer than 1 in 100 people), an allergic reaction, coughing, or a slow heart rate and blood pressure may occur at the time of administration. The anesthesiologist can monitor and provide medications to counteract this reaction. After the contrast fluid (indocyanine green) is administered, thyroid studies using radioactive iodine cannot take place for one week.

Finally, you will be under anesthesia for an additional 7-10 minutes. However, there are no significant risks associated with this brief additional period of anesthesia, considering the overall length of anesthesia for this procedure.

5. Voluntary Participation

You decide whether or not to participate in the study, and participation is entirely voluntary. If you choose not to participate, you will receive the standard surgery, meaning normal abdominal pressure with standard muscle relaxation. You have at least one week to consider your decision. You will be contacted before the surgery to ask if you wish to participate. If you decide to participate, you can withdraw at any time, without needing to provide a reason. This will never have any negative impact on your treatment. If any new information arises during the study that is important for you, the researcher will inform you, and you will be asked whether you still wish to participate.

The study will stop 3 months after the surgery, or sooner if you choose to withdraw, if the researcher determines it is better for you to stop, or if the ethics committee decides to halt the study.

6. Confidentiality of Data

Your personal data and blood samples will be collected, used, and stored in a coded form. Your medical and personal data may be viewed by the researchers, the Health and Youth Inspectorate, the medical ethics review committee, and auditors who check if the study is being conducted properly and reliably. We take great care to handle your information as required by data protection laws and the privacy regulations of Radboudumc. Your information will be stored for the legal retention period of 15 years. We would like to store your blood and tissue for an additional 5 years to potentially conduct further measurements, especially related to immune system research.

On the consent form, you can indicate whether you agree to this. You can withdraw your consent for the use of your personal data and biological material at any time by contacting the research team. They are responsible for processing your data. Data already collected will still be used in the study. If you wish, your blood and tissue can be destroyed after the study, but any measurements already made will be used.

For more information about your rights regarding your personal data, you can consult the website of the Dutch Data Protection Authority www.autoriteitpersoonsgegevens.nl or the data protection officer at Radboudumc (---@radboudumc.nl).

We will send a letter to your general practitioner and treating specialists informing them that you are participating in this study.

7. Insurance

For all participants in this study, Radboudumc has taken out insurance. This insurance covers any harm caused by participation in the study, both during the study or up to four years after your participation. Any harm must be reported to the insurer within four years. However, the insurance does not cover all types of damage. At the end of this letter, you will find a summary of what is not covered. These conditions are outlined in the "Regulation on compulsory insurance for medical-

scientific research with humans," which is available at www.ccmo.nl, the website of the Central Committee on Research Involving Human Subjects.

The insurance offers coverage of €650,000 per participant, €5,000,000 for the entire study, and €7,500,000 per year for all studies by the same sponsor. The insurance is with Centramed. Claims should be submitted to Centramed B.A., PO Box 7374, 2701 AJ, Zoetermeer.

The insurance does not cover:

- Damage from a risk about which you have been informed in the written information (unless the risk is more severe than expected or unlikely);
- Damage to your health that would have occurred even if you had not participated in the study;
- Damage from not fully following instructions or guidance;
- Damage to your descendants resulting from a negative effect of the study on you or them;
- Damage from an existing treatment method during research on existing treatments.

8. Do You Have Any Questions?

If you have any questions after reading this letter, you can contact the research team:

Dr. GTJA Reijnders-Boerboom, Medical Researcher

Dr. MC Warlé, Vascular and Transplant Surgeon, Radboudumc

Surgery Department

PO Box 9101, 6500 HB Nijmegen

Or the independent doctor:

Prof. Dr. M. Edwards (Radboudumc, Surgery Department)

If you are not satisfied with the research or treatment, you can contact the independent complaints committee of CWZ by phone: 024-3657300 or by email: klantenservice@cwz.nl

For complaints about the protection of your personal data, you can contact the Data Protection Officer at CWZ. Phone: 024-3658949 or email: FG@cwz.nl

9. Signing the Consent Form

If you give your consent, we will ask you to confirm this in writing on the accompanying consent form. By signing, you indicate that you have understood the information and agree to participate in the study.

Both you and the researcher will receive a signed version of this consent form.

Thank you for your attention!

RECOVER 2 Study Consent Form

The effect of low-impact laparoscopy versus standard laparoscopy during robot-assisted prostatectomy on recovery quality and the immune system.

- I have read the information sheet. I was able to ask questions, and my questions have been sufficiently answered. I had enough time to decide whether I want to participate.
- I understand that participation is voluntary, and I can decide at any time to withdraw without giving a reason.
- I consent to informing my GP and treating specialists about my participation in this study.
- I consent to allowing the research team, health inspectors, auditors, or members of the ethics committee to access my medical and research data.
- I consent to the collection and use of my data, blood, and tissue for the purposes outlined in the information sheet.
- I consent to my data being stored at the research location for 15 years after the study.
- I consent / do not consent* to my blood and tissue being stored at the research location for 5 years after the study for potential future measurements.

I consent to participating in the above-mentioned study.

Participant's Name: _____

Signature: _____

Date: __ / __ / __

Researcher's Declaration:

I declare that I have fully informed this participant about the study mentioned. If new information arises during the study that could influence the participant’s consent, I will inform them in a timely manner.

Researcher's Name (or representative): _____

Signature: _____ Date: __ / __ / __

*Cross out what does not apply.

The participant will receive a full information sheet along with a signed copy of the consent form.

Let me know if you need any further clarification!