Informed Consent Form– Control Patient

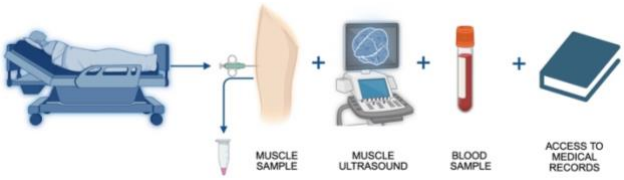
INFORMED CONSENT FORM
Effect of Physical Therapy on NLRP3 Inflammasome Activation and Muscle Atrophy in Critical Illness Myopathy

- Sponsors: Dra. Lilian Jara Sosa, Dra. Paola Llanos Vidal, Dra. Denisse Valladares Ide
- Principal Investigator Óscar Arellano Pérez
- Rut 17.285.871-6
- Institution: Hospital de Urgencia y Asistencia Pública – Clínica INDISA Providencia - Biomedical Sciences Institute, Faculty of Medicine, University of Chile
- Phone: +56961479414
- Email: oscar.arellano@ug.uchile.cl
- Address: Avenida Independencia 1027, Comuna de Independencia, Santiago.

Invitation to participate: You are invited to participate in the research project titled "Effect of Physical Therapy on NLRP3 Inflammasome Activation and Muscle Atrophy in Critical Illness Myopathy" because some ICU patients are at risk of developing muscle weakness and motor sequelae. To study diseased muscle, it is necessary to compare it with healthy muscle. You are among those patients who are not at risk of developing this condition and therefore are extremely valuable for comparative purposes. The data from your samples will be compared with those of patients diagnosed with the target myopathy.

Objectives: The objective of this study is to investigate the mechanisms that occur in ICU patients' muscles that lead to weakness, muscle mass loss, and disability. To counter these effects, we will study the role of physical therapy in improving muscle strength in ICU patients. A total of 24 patients from the Hospital de Urgencia y Asistencia Pública and Clínica INDISA Providencia will be included.

Procedures: **Muscle sample:** A sample will be taken from one of your thigh muscles (vastus lateralis) using a needle approximately 2 mm in diameter. The procedure will be performed under local anesthesia by ICU physicians. **Blood sample:** A blood sample will be drawn from one of your existing venous lines placed for hospitalization. **Muscle ultrasound:** Images of your thigh muscles will be taken using a portable ultrasound device. **Access to medical records:** Clinical data related to your hospitalization will be collected and recorded.



Risks: Possible complications from participation in this study include those related to the muscle biopsy, such as bruising, swelling, pain at the biopsy site, or bleeding. These events will be monitored by the principal investigator and an ICU clinical nurse, who will supervise nursing care of the biopsy site.

Costs: There is no cost for study participants. The study materials will be provided by the research team. Any treatments or complications unrelated to the study must be financed by you or your health insurance.

Benefits: There is no direct benefit to you. However, the study will generate information about the development of muscle weakness and muscle mass loss in ICU patients. This information is crucial for the generation of knowledge and future treatments to combat this weakness and

physical disability. Therefore, the study will contribute valuable information to scientific and societal development.

Compensation: There is no financial compensation for participating in this study.

Insurance: If you suffer any complication directly associated with the muscle biopsy, medical professional liability insurance will be available.

Confidentiality: All information collected from your medical history will be under the custody of the principal investigator. To ensure confidentiality, data will be stored in the REDCap system (Research Electronic Data Capture), which provides strict user-level access to protect patient information. Results will always be presented anonymously. Your identity and any identifying data will not be disclosed to third parties. Muscle and blood samples will be stored at the Muscle Metabolism Laboratory at the Universidad de Chile under the custody of Dr. Paola Llanos Vidal. Samples will be stored for 3 years. No additional tests beyond those proposed in this research will be conducted. If you do not agree to the storage of unused samples, they will be properly discarded.

Use of research results: The results of this study are not intended for commercial purposes. They will be used in the doctoral thesis of the principal investigator and may be published in scientific journals.

Additional information: You and your attending physician may access any significant information that arises during the study. Based on this information, you may choose to withdraw or continue participation.

Voluntariness: Participation in this research is entirely voluntary. You may withdraw at any time by informing the principal investigator. This will not affect the care or treatment you receive for your condition. Similarly, your treating physician or the investigator may recommend your withdrawal from the study.

Complications: In the unlikely event that you suffer complications directly resulting from the muscle biopsy, you will receive complete medical treatment for that complication, covered by medical professional liability insurance, at no cost to you or your insurance. This does not include complications resulting from your primary illness or its natural course.

Rights: You will receive a full, signed copy of this document. If you require any further information or wish to know the results of the study, you may contact:
Investigator: Óscar Arellano Pérez, Phone: +56961479414, Email: oscar.arellano@ug.uchile.cl
Institutional Authorities:
Director of the Hospital de Urgencia y Asistencia Pública, Dr. Patricio Raúl Barría Ailef, Email: patricio.barria@redsalud.gob.cl
Medical director of Clínica INDISA, Dr. Rodrigo Castillo Darvich, Email: rodrigo.castillo@indisa.cl

Additional Participant Rights: If you have any questions or concerns regarding your rights, President of the "Human Research Ethics Committee" (CEISH): Dr. Lucía Cifuentes O. Phone: +56 2 2978 9536 Email: ceish.med@uchile.cl Office located next to the Central Library of the Faculty of Medicine, Universidad de Chile, Av. Independencia 1027, Commune of Independencia.
President of the "Scientific Ethics Committee of the Central Metropolitan Health Service" (CEC-SSMC): Dr. Rafael Mendizábal R. Phones: +56 2 2574 6958 – +56 2 2574 3520 Email: comite.eticossmc@redsalud.gob.cl Office located at Villavicencio 361, 1st floor, Commune of Santiago.

President of the “Scientific Ethics Committee of Clínica INDISA”: Mr. Gonzalo Castillo B. Phone: +56 2 2362 5243 Email: cec@indisa.cl Office located at Santa María 1810, Commune of Providencia.

Declaration of Consent: After having read and understood the information in this document and having resolved all my doubts, I give my consent for my relative’s participation in this study.

Participant’s Name: _____ Rut:_____

Rut:_____ Signature:_____ Date: __ / __ / __

Institution Director/Delegate: _____

Rut:_____ Signature:_____ Date: __ / __ / __

Investigator’s Name: _____

Rut:_____ Signature:_____ Date: __ / __/ __

Reviewed and approved by: _____ Date: __ / __ / __

Reviewed and approved by: _____ Date: __ / __ / __

Reviewed and approved by: _____ Date: __ / __ / __

Informed Consent for the Legal Guardian of a Patient with Critical Illness Myopathy

INFORMED CONSENT FORM
Effect of Physical Therapy on NLRP3 Inflammasome Activation and Muscle Atrophy in Critical Illness Myopathy

- Sponsors: Dra. Lilian Jara Sosa, Dra. Paola Llanos Vidal, Dra. Denisse Valladares Ide
- Principal Investigator Óscar Arellano Pérez
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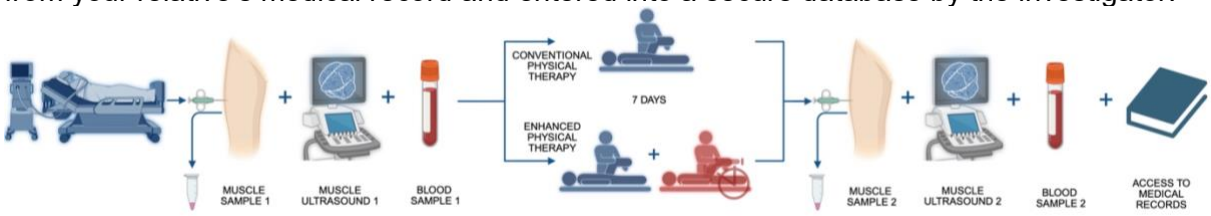
- Phone: +56961479414
- Email: oscar.arellano@ug.uchile.cl
- Address: Avenida Independencia 1027, Comuna de Independencia, Santiago.

Invitation to participate: We are inviting you to participate in the research project titled "Effect of Physical Therapy on NLRP3 Inflammasome Activation and Muscle Atrophy in Critical Illness Myopathy," because due to their hospitalization in the ICU, your family member is among those at risk of developing muscle weakness. This is caused by several factors specific to the ICU setting, such as bed rest, the use of certain medications, and the severity of the illness.

Objectives: This research aims to study the changes that occur in the muscle of ICU patients which lead to weakness, muscle mass loss, and disability. To counteract these effects, the role of physical therapy in ICU patients will be studied to determine whether it helps improve muscle strength. The study will include a total of 24 patients from the Hospital de Urgencia y Asistencia Pública and Clínica INDISA Providencia in the Metropolitan Region.

Procedures: **Muscle sample:** Two samples will be taken from one of the thigh muscles (vastus lateralis) using a needle approximately 2 mm in diameter. This procedure will be performed using local anesthesia by ICU physicians. The same procedure will be repeated seven days later by the same medical team. **Blood sample:** Two blood samples will be taken. These samples will be obtained using existing venous access, so no additional puncture will be required. **Physical therapy:** During hospitalization in the ICU, your relative may receive more physical therapy sessions than those typically received in the ICU, using a cycle ergometer placed at the foot of the bed. Assignment to the intervention or control group will be random and based on sex and age. **Muscle ultrasound:** Muscle images of the anterior thigh will be taken using a portable ultrasound device. **Clinical records:** Clinical data will be obtained from your relative's medical record and entered into a secure database by the investigator.



Risks: The most frequent complications related to the muscle sample collection are bruising, swelling, and pain at the site. There may also be a low risk of bleeding. These risks will be minimized and managed by the principal investigator in coordination with ICU nurses and physicians.

Costs: There is no cost for participation. The materials needed for the study will be provided by the research team. All other treatments, not part of the study, must be financed by the participant or their health insurance provider.

Benefits: There is no direct benefit for participating in this study. However, this research will help better understand muscle dysfunction in ICU patients and how to prevent it through early physical therapy.

Compensation: There is no monetary compensation. Participation may help identify early muscle dysfunction and assist in clinical decision-making.

Insurance: The study includes medical professional liability insurance. This insurance will cover any complication resulting directly from the procedure, such as infection or bleeding.

Confidentiality: The data collected during the study will be kept confidential and used exclusively for research purposes. All personal information will be entered into a secure platform (REDCap), with access restricted to authorized users only. Results will be published anonymously. Samples will be stored at the Muscle Metabolism Laboratory of Universidad de Chile under the supervision of Dr. Paola Llanos Vidal for up to three years.

Use of results: The results will not be used for commercial purposes. They will be part of a doctoral thesis and may be published in scientific journals or presented at conferences.

Additional information: You, your family, or your relative's physician may access the study data. If at any time you or your family wish to withdraw from the study, you may do so without explanation. The study team will answer any questions.

Voluntary participation: Participation is voluntary. If you decide not to participate or to withdraw your relative from the study, they will continue to receive all necessary medical care without any prejudice. If the patient regains consciousness, they will be asked for their consent to continue participation. If they do not agree, their participation will be terminated, and their data and samples will be destroyed.

Complications: Any complications arising from the procedure will be treated at no cost to the participant through the medical professional liability insurance. This does not include complications related to their underlying illness.

Rights: You and your family member will receive a complete, written, and signed copy of this document. If you require any additional information about your participation in this study or wish to know the results, you may contact:

Investigator:

Óscar Arellano Pérez, Phone: +56 9 6147 9414, Email: oscar.arellano@ug.uchile.cl

Institutional Authorities:

Director of the Hospital de Urgencia y Asistencia Pública, Dr. Patricio Raúl Barría Ailef, Email: patricio.barria@redsalud.gob.cl

Medical Director of Clínica INDISA, Dr. Rodrigo Castillo Darvich, Email: rodrigo.castillo@indisa.cl

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Declaration of Consent: After having read and understood the information in this document and having resolved all my doubts, I give my consent for my relative’s participation in this study.

Participant’s Name: _____ Rut:_____

Legal Guardian’s Name: _____

Rut:_____ Legal Guardian’s Signature:_____ Date: __ / __ / __

Institution Director/Delegate: _____

Rut:_____ Signature:_____ Date: __ / __ / __

Investigator’s Name: _____

Rut:_____ Signature:_____ Date: __ / __/ __

Reviewed and approved by: _____ Date: __ / __ / __

Reviewed and approved by: _____ Date: __ / __ / __

Reviewed and approved by: _____ Date: __ / __ / __

Informed Con1sent Form– Patient Confirmation Post Legal Guardian Authorization

INFORMED CONSENT FORM
Effect of Physical Therapy on NLRP3 Inflammasome Activation and Muscle Atrophy in Critical Illness Myopathy

- Sponsors: Dra. Lilian Jara Sosa, Dra. Paola Llanos Vidal, Dra. Denisse Valladares Ide
- Principal Investigator Óscar Arellano Pérez
- Rut 17.285.871-6
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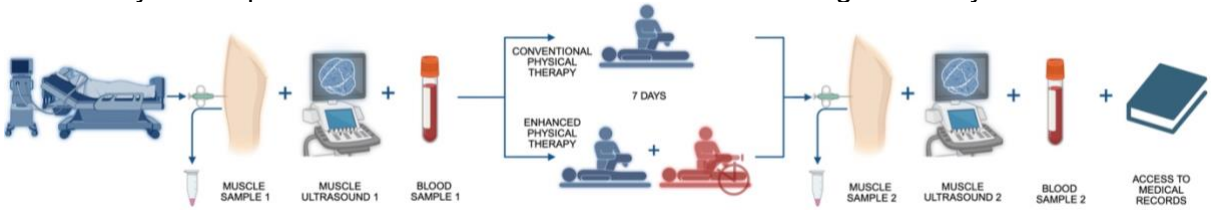
- Phone: +56961479414
- Email: oscar.arellano@ug.uchile.cl
- Address: Avenida Independencia 1027, Comuna de Independencia, Santiago.

Invitation to participate: You were included in the research project titled "Effect of Physical Therapy on NLRP3 Inflammasome Activation and Muscle Atrophy in Critical Illness Myopathy" because, due to your ICU hospitalization, you were among the patients at risk of developing muscle weakness. This condition occurs due to several ICU-related factors, including prolonged bed rest, the use of certain medications, and the severity of the illness. Previously, your legal guardian authorized your participation. Now that you have regained consciousness and possess the physical and mental capacity to decide, we invite you to continue participating in this study.

Objectives: This study aims to examine the changes that occur in the muscles of ICU patients that lead to weakness, reduced muscle mass, and disability. To counteract these effects, the study will evaluate the role of physical therapy in ICU patients to improve muscle weakness. A total of 24 patients will be included from the Hospital de Urgencia y Asistencia Pública and Clínica INDISA Providencia in the Metropolitan Region.

Procedures: **Muscle sample:** During your participation in this study, two samples were taken from one of your thigh muscles (vastus lateralis) using a needle approximately 2 mm in diameter. This procedure was performed with anesthetics to prevent pain and was carried out by ICU physicians. The procedure was repeated 7 days later. **Blood sample:** Two blood samples were taken from venous access already in place due to your hospitalization. **Physical therapy:** Upon enrollment, you may have received more frequent physical therapy sessions than usual, or the standard sessions normally provided. If you received more sessions, these were carried out using a recumbent cycling device for ICU patients. This was done to study the effects of extended physical therapy on muscle weakness. Although assignment was random, your age and sex were considered to ensure similarity between groups. Allocation was not based on ethnicity. **Muscle ultrasound:** Additionally, images of your thigh muscles were taken using a portable ultrasound device. **Access to medical records:** Clinical data related to your hospitalization were collected and recorded during this study.



Risks: If you experienced any complications during participation, they were likely due to the muscle biopsy procedure, including bruising, swelling, pain at the biopsy site, or bleeding.

These events were monitored by the principal investigator and an ICU clinical nurse, who supervised nursing care of the biopsy site on your leg.

Costs: There is no cost to participate in this study. All study materials were provided by the research team. Treatment of illnesses or complications unrelated to the study must be covered by you or your health insurance.

Benefits: This study offers no direct benefit to you. However, it will provide insight into how muscle weakness and loss of muscle mass develop in ICU patients. This information is important for generating knowledge and future treatment strategies for physical disability in ICU patients. Therefore, this study will provide valuable data for scientific development and society.

Compensation: There is no economic compensation for participating. However, the information obtained about your muscular condition may help detect ICU-related muscle weakness and allow physicians to manage this condition using a comprehensive and multidisciplinary approach, if needed.

Insurance: In the event of a complication directly related to the muscle biopsy, medical professional liability insurance will be available.

Confidentiality: All information from your medical history was collected and remains under the custody of the principal investigator. To ensure confidentiality, participant data were entered into REDCap (Research Electronic Data Capture), a secure system with strict user-level access permissions to protect patient information. Results will always be reported anonymously. Your identity and no identifying data will be disclosed to third parties. Muscle and blood biopsy samples were sent to the Muscle Metabolism Laboratory at the Universidad de Chile under the custody of Dr. Paola Llanos Vidal. The samples will be stored for 3 years. No additional tests will be performed beyond those proposed in the study. If you do not agree to the storage of remaining samples, they will be appropriately discarded.

Use of research results: The results of this study will not be used for commercial purposes. They will be used for the doctoral thesis of the principal investigator and scientific publications.

Additional information: You and your attending physician may access any relevant information that arises during the study. Based on this, you may choose to withdraw or continue your participation.

Voluntariness: Participation in this study is completely voluntary. You may withdraw at any time by informing the principal investigator, without affecting your medical care. Likewise, your physician or the investigator may suggest that you withdraw from the study.
Complications: If you experienced complications directly related to the muscle biopsy, you received or will receive full medical treatment for that complication, covered by medical professional liability insurance at no cost to you or your insurance. This does not include complications related to your illness or its natural course.

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Investigator's Name: _____

Rut:_____ Signature:_____ Date: __ / __/ __

Reviewed and approved by: _____ Date: __ / __ / __

Reviewed and approved by: _____ Date: __ / __ / __

Reviewed and approved by: _____ Date: __ / __ / __

Informed Consent Form patient with Critically Illness Myopathy

INFORMED CONSENT FORM
Effect of Physical Therapy on NLRP3 Inflammasome Activation and Muscle Atrophy in Critical Illness Myopathy

- Sponsors: Dra. Lilian Jara Sosa, Dra. Paola Llanos Vidal, Dra. Denisse Valladares Ide
- Principal Investigator Óscar Arellano Pérez
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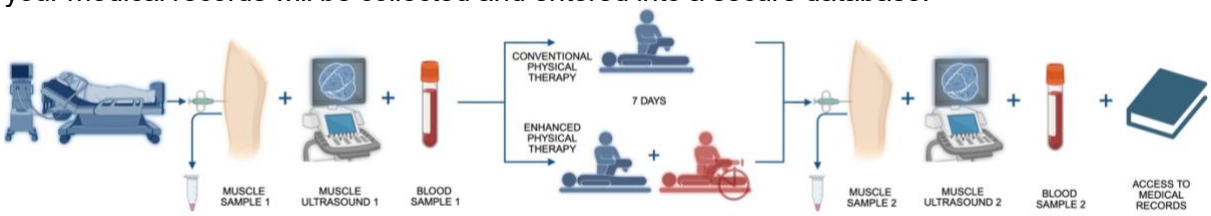
- Phone: +56961479414
- Email: oscar.arellano@ug.uchile.cl
- Address: Avenida Independencia 1027, Comuna de Independencia, Santiago.

Invitation to participate: We invite you to participate in the research project "Effect of Physical Therapy on NLRP3 Inflammasome Activation and Muscle Atrophy in Critical Illness Myopathy" because, due to your hospitalization in the ICU, you are among the patients at risk of developing muscle weakness. This occurs due to several factors inherent to ICU stays, such as bed rest, the use of certain drugs, and the severity of the illness.

Objectives: This research aims to study the phenomena that occur in the muscles of ICU patients that cause weakness, loss of muscle mass, and disability. To counteract these effects, the role of physical therapy will be studied in ICU patients to determine if it can improve muscle weakness. The study will include a total of 24 patients from the Hospital de Urgencia y Asistencia Pública and Clínica INDISA Providencia in the Metropolitan Region.

Procedures: **Muscle sample:** Two samples will be taken from one of your thigh muscles (vastus lateralis) using a needle approximately 2 mm in diameter. This procedure will be performed under local anesthesia by ICU doctors. The same procedure will be repeated after 7 days. **Blood sample:** Two blood samples will be taken from one of the venous access lines already installed due to your hospitalization. **Physical therapy:** Upon entering the study, you may receive more frequent physical therapy sessions from ICU physiotherapists than usual, or you may receive the standard care. If you receive additional therapy, a cycle ergometer designed for bedridden ICU patients may be used. The goal is to study the effect of prolonged physical therapy on muscle weakness. Although the assignment will be random, age and sex will be considered to ensure the groups are as similar as possible. The allocation will not depend on ethnicity. **Muscle ultrasound:** Images of your thigh muscles will also be taken using a portable ultrasound device. **Medical record access:** During this study, clinical data from your medical records will be collected and entered into a secure database.



Risks: The most common complications from muscle biopsy are bruising, swelling, and pain at the site. There may also be a low risk of bleeding. These risks will be minimized and managed by the principal investigator in coordination with ICU nursing and medical staff.

Costs: There is no cost to participate in this study. All study-related materials will be provided by the research team. Any treatment unrelated to the study must be financed by you or your health insurance.

Benefits: There is no direct benefit to you. However, this study may help understand and address ICU-acquired muscle dysfunction and how to prevent it through early physical therapy.

Compensation: There is no monetary compensation. Participation may help detect early muscle dysfunction and contribute to improving ICU patient care.

Insurance: This study includes medical professional liability insurance that will cover any complication directly related to the procedure, such as infection or bleeding.

Confidentiality: Data collected during the study will be kept confidential and used exclusively for research purposes. All information will be entered into a secure platform (REDCap), with access restricted to authorized users. Results will be published anonymously. Samples will be stored at the Universidad de Chile's Muscle Metabolism Laboratory under the supervision of Dr. Paola Llanos Vidal for up to three years.

Use of results: The results will not be used for commercial purposes. They will be part of a doctoral thesis and may be published in scientific journals or presented at academic conferences.

Additional information: You, or your attending physician may access study information. You may withdraw from the study at any time, without giving a reason. The research team will answer any questions you may have.

Voluntary participation: Participation in this study is entirely voluntary. If you choose not to participate or to withdraw, your medical care will not be affected. If you regain consciousness and can understand this information, you will be asked whether you agree to continue. If you do not agree, your participation will end, and all related data and samples will be destroyed.

Complications: Any complications from the biopsy will be treated at no cost under the medical professional liability insurance. This does not apply to complications related to your primary illness.

Rights: You will receive a full, signed copy of this document. If you require any further information or wish to know the results of the study, you may contact:
Investigator: Óscar Arellano Pérez, Phone: +56961479414, Email: oscar.arellano@ug.uchile.cl
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Participant's Name: _____ Rut:_____

Rut:_____ Signature:_____ Date: __ / __ / __

Institution Director/Delegate: _____

Rut:_____ Signature:_____ Date: __ / __ / __

Investigator's Name: _____

Rut:_____ Signature:_____ Date: __ / __/ __

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