INFORMED CONSENT FORM

OFFICIAL TITLE:

Fluid Removal With a High Rate Ultrafiltration Protocol in Patients With Intravascular Congestion: the FILTRATE Trial

NCT NUMBER:

NCT Pending

ORGANIZATION'S UNIQUE PROTOCOL ID:

NF26-00006

STUDY START DATE:

04/06/2026

ADDRESS

Monterrey, N.L., México

INFORMED CONSENT FORM

Title of the Study	Fluid Removal With a High Rate Ultrafiltration Protocol in Patients With Intravascular Congestion: the FILTRATE Trial
Name of Principal Investigator	Dr. Mónica Sánchez Cárdenas
Service / Department	Nephrology
Research site address	Av. Francisco I. Madero SN, Colonia Mitras Centro
Contact Phone Number (24 hours/emergencies)	8180911271
Contact person	Dr. Edgar Adrián Montemayor Garza
Name and address of the emergency care institution	University Hospital "Dr. José Eleuterio González". Av. Francisco I. Madero SN, Colonia Mitras Centro
Document Version	Version 3
Document Date	08/05/2026

You have been invited to participate in a research study. This document contains important information about the purpose of the study, what you will do if you decide to participate, and how we would like to use your personal and health information.
May contain words you do not understand. Please ask your doctor or study staff to explain any words or information that are unclear.

1. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to determine if patients with Chronic Kidney Disease who are hospitalized for hemodialysis for ultrafiltration (water removal) due to fluid overload, tolerate in an equivalently safe and effective manner a faster fluid removal (high ultrafiltration rate) during a session.

You are asked to participate because your input is of utmost importance in comparing the results of standard rate fluid removal against higher rate removal.

The research in which you will participate is important because the results obtained are expected to modify the traditional prescription of ultrafiltration, finding evidence of adequate safety and efficacy, with a correct evolution of patients and without a higher frequency of adverse events.

2.- WHAT WILL BE THE DURATION OF THE STUDY AND HOW MANY PARTICIPANTS WILL THERE BE IN THIS STUDY?

The total duration of the study is estimated to be 17 months.

Seventy research participants will be included at this center.

Their participation will last only as long as their hospital stay and their exposure to the intervention to be studied will only be during the first hemodialysis/ultrafiltration session.

3.- WHAT ARE THE REQUIREMENTS THAT WILL BE TAKEN INTO ACCOUNT FOR MY PARTICIPATION?

You may be able to participate if : You have an urgent need to undergo a hemodialysis session due to fluid overload with the presence of pulmonary edema ("water in the lungs"), as well as ultrasound data of excess body fluids at the circulatory level, as well as excess pressures in your circulatory system.

Meeting the following criteria:
1. Be Male or Female >18 years old
1.1. Suffering from Chronic Kidney Disease on hemodialysis with at least 3 months of starting this Renal Replacement Therapy, with need for mechanical ultrafiltration due to fluid overload.
1.2. First session since hospital admission
1.3. Echocardiogram evidence of elevated filling pressures evaluated by a cardiologist.
1.4. Ultrasound evidence of intravascular congestion in various organs (Evaluated by a nephrologist or cardiologist):
1.4.1. Evidence of Pulmonary Congestion (Water in the lungs)
1.4.2. Evaluation with VExUS protocol (Which consists of ultrasound on the skin to visualize the pulse of the blood vessels through the liver)
1.5. Hemodynamic stability with blood pressure of at least >120/80 mmHg

You will not be able to participate if you have any of these characteristics:
Present hemodynamic instability (<100/60)
Present in cardiogenic shock
Present in septic or distributive shock
Present with acute coronary syndrome (e.g., heart attack)
Present with pericardial effusion with hemodynamic compromise and tamponade physiology (Water around the heart)
Presenting with a known right ventricular dysfunction
Present with intestinal bleeding
Patients with poor ultrasound window (inability to visualize internal structures or organs)
Having a known pulmonary pathology
Having severe heart valve disease
Being a pregnant woman

4. WHAT IS THE TREATMENT IN THE STUDY?

If you decide to participate in this research study, your treatment will consist of a hemodialysis session with the main objective of fluid removal. You may be randomly assigned to the standard ultrafiltration group of 10 ml/kg/h or the high ultrafiltration group >13 ml/kg/h.

The assignment to one group or the other will be random, that is, you will not know which of the 2 groups you were assigned to.

5. WHAT PROCEDURES WILL BE PERFORMED ON ME?

If you agree to participate in this study, you will undergo a specialized evaluation process to confirm that you meet the necessary medical criteria. The procedures are as follows:

Eligibility Assessment (Congestion Confirmation): Before being assigned to a group, the Nephrology and Cardiology team will perform a detailed assessment of your circulatory status. The following will be used for this assessment:

Pulmonary and Vascular Ultrasound (VExUS): We will look for evidence of excess fluid within your blood vessels and lungs by measuring the diameter of your veins and blood flow in organs such as the liver and kidney.

Echocardiogram: Your heart's filling pressures (flow rates and internal pressures) will be measured.

Only if these tests confirm a specific elevation of intravascular pressures and congestion, and if your blood pressure remains stable (greater than 120/80 mmHg), will you be able to continue in the study.

Technical Calculations and Weighing: Once your inclusion is confirmed, you will be weighed on a calibrated scale and a bioimpedance (placement of sensors on the skin) will be performed solely to accurately calculate the fluid elimination goal.

Study Group Assignment (Randomization): You will be randomly assigned (by lottery) to one of the two treatment groups:

Standard ultrafiltration group: Removal of fluid at 10 ml per kilogram of body weight per hour.

High ultrafiltration group: Removal of fluid at a higher rate (>13 ml per kilogram of body weight per hour).

Hemodialysis Session and Safety Monitoring: During the session, your blood pressure and pulse will be measured every 15 to 30 minutes. The medical team will closely monitor for any symptoms (dizziness, cramps, or nausea). Following international safety standards, if your blood pressure drops below the established limits or you experience discomfort, the session will be adjusted or stopped immediately.

24-Hour Reassessment: Exactly 24 hours after the session ends, we will repeat the ultrasound and echocardiogram tests to objectively measure how your heart pressures and lung congestion responded to the treatment. We will also evaluate your oxygen levels and any improvement in your breathing.

Follow-up and Analysis: We will collect your laboratory test results (such as the cardiac marker NT- proBNP) and review your medical record until you are discharged to document your complete progress.

6. -WHAT WILL YOU DO IF YOU DECIDE TO PARTICIPATE IN THIS STUDY?

If you decide to participate, your role in the research will consist of the following:

Remain under observation: You must be available for ultrasound and echocardiography assessments at scheduled times (at the beginning and 24 hours after treatment).

Follow the staff's instructions: During the hemodialysis session, you must remain at rest as directed by the medical and nursing staff, and allow frequent monitoring of your blood pressure and other vital signs.

Constant communication: Your most important responsibility is to immediately inform the doctor or nurse about any changes in how you feel during the session. You must specifically report if you experience:

- *Dizziness or feeling faint.*
- *Nausea or the urge to vomit.*
- *Muscle cramps or extreme weakness.*
- *Chest pain or difficulty breathing.*
- *Tingling or numbness in hands, feet or face.*

Authorize the use of your information: You allow the data obtained from your studies (ultrasound, laboratories and clinical record) to be analyzed confidentially by the researchers.

7.- WHAT ARE THE POSSIBLE RISKS OR INCONVENIENCES?

Participation in this study involves certain risks related to the rate at which fluid is removed from your body. Depending on the group you are assigned to, these risks may include:

Risks related to faster liquid removal (High Ultrafiltration Group):

Instability in your blood pressure: The main risk is that your blood pressure may drop significantly during the session (hypotension), which could cause dizziness, nausea, cramps, or headache.

Stress on the heart: Very rapid elimination of fluids can cause temporary excessive strain on the heart muscle (known as myocardial stunning).

Impact on other organs: In patients who still have some kidney function, there is a risk that this function will decline more rapidly due to insufficient blood flow during the session. There is also a rare risk of impaired circulation to the intestines or brain in people with a history of vascular disease.

Risks related to conventional liquid disposal (Standard Ultrafiltration Group):

Persistent congestion: Removing fluid more slowly can lead to excess water remaining in your system, which can cause severe breathing difficulties (pulmonary edema) or the need for oxygen for a longer period.

Overload damage: Excess fluid in the veins can impair the function of your liver and intestines, and in the long term, increase the risk of heart complications.

Security and Mitigation Measures:
To reduce these risks, the study has the following safeguards:

Continuous Medical Monitoring: You will be monitored second by second by trained personnel.

Immediate Interruption Criteria: The session will be stopped or adjusted if your systolic blood pressure drops by more than 20 mmHg or if you experience symptoms such as extreme dizziness, heart rhythm disturbances, or any signs of confusion.

Safety Limits: We have established strict limits to ensure that, even in the rapid withdrawal group, speed does not exceed levels considered safe under close supervision.

8. WHAT ARE THE POTENTIAL BENEFITS FOR YOU OR OTHERS?

The potential benefits for you from this study include equivalent clinical improvement in dyspnea (shortness of breath), need for supplemental oxygen, blood pressure control, and possibly even a shorter hospital stay and faster recovery to hospital discharge.

Participation in this study may help physician scientists better understand how patients on hemodialysis behave during an ultrafiltration session at a higher than standard rate when they present ultrasound data of marked intravascular congestion and increased cardiac filling pressures.

9. -WHAT OTHER PROCEDURES OR TREATMENTS MIGHT BE AVAILABLE TO YOU?

You do not have to participate in this research study if you do not wish to. *In your case, you will receive the necessary treatment to control the reason for your hospitalization.*

10. WILL YOUR PARTICIPATION IN THIS STUDY INCUR ANY COST TO YOU?

There will be no costs for you to participate in this study.

Any expenses incurred during your participation in this study will be covered by its budget.

11. WILL YOU BE PROVIDED WITH ANY FINANCIAL COMPENSATION FOR TRANSPORTATION EXPENSES?

You will not receive any payment or salary for participating in this study.

12.- WILL BLOOD OR TISSUE SAMPLES BE STORED FOR FUTURE RESEARCH OR FOR GENETIC TESTING?

No blood or tissue samples will be taken or stored during the study or for future research, nor will genetic testing be performed.

13. WHAT SHOULD YOU DO IF SOMETHING HAPPENS TO YOU AS A RESULT OF PARTICIPATING IN THIS STUDY?

If you suffer an injury or illness during your participation in the study, you must inform the study doctor immediately so that appropriate intervention can be made.

The expenses generated by such injury or illness will only be paid if the study physician has determined that the injury/illness is directly related to the study procedures, and is not the result of a pre-existing condition, the normal progression of your disease, or because the instructions recommended by the study physician have not been followed.

If the injury or disability warrants it and/or if applicable, you will be granted the compensation to which you are legally entitled.

14.- WHAT ARE YOUR RIGHTS AS A RESEARCH PARTICIPANT?

If you decide to participate in this study, you have the right to be treated with respect and honesty, and your safety will be guaranteed at all times. Your main rights include:

Freedom of participation: You are free to withdraw your consent and end your participation in this study at any time, without needing to give explanations and without this affecting in any way your relationship with the doctors or the quality of medical care you receive at this institution.

Right to updated information: You have the right to be informed in a timely manner about any findings, discoveries or new information that arises during the development of the study (already (whether regarding the safety or efficacy of the treatments). This will be respected even if such information could affect your willingness to continue participating in the research. In such a case, the situation will be explained to you in detail so that you can freely and voluntarily decide whether you wish to remain in the study or withdraw.

Privacy: Right to have your personal data and clinical results handled with strict confidentiality

15.- CAN YOU END YOUR PARTICIPATION AT ANY TIME DURING THE STUDY?

Your participation is strictly voluntary. If you wish to withdraw from the study, you may do so at any time by notifying the principal investigator in writing. If you choose not to participate or withdraw from the study, your current and/or future medical care will not be affected, and you will not incur any penalties or lose any benefits to which you would otherwise be entitled.

Your participation may also be suspended or terminated by the study physician, without your consent, for any of the following circumstances:

- *That the study has been cancelled.*
- *That the doctor considers it best for you.*
- *That he needs some procedure or medication that interferes with this research.*
- *That he has not followed the doctor's instructions, which could lead to health problems.*

If you decide to withdraw from this study, you must do the following:

- *Notify your treating physician about the study*

If your participation in the study is terminated for any reason, for your safety, your doctor will continue with clinical follow-up. In addition, your medical information collected up to that point may be used for research purposes.

16.- HOW WILL THE CONFIDENTIALITY OF YOUR PERSONAL DATA AND THE INFORMATION IN YOUR MEDICAL RECORD BE PROTECTED?

If you agree to participate in the research, the study physician will collect and record confidential personal information about your health and treatment. This information will not include your full name or address, but may include other information about you, such as your initials and date of birth. All of this information is intended to ensure the scientific integrity of the research. Your name will not be disclosed outside the institution unless required by law.

You have the right to control the use of your personal data in accordance with the Federal Law on the Protection of Personal Data Held by Private Parties, as well as to request access to, correction of, and objection to the processing of your personal information. Your request will be processed in accordance with current data protection regulations. However, certain information may not be available until the study is completed, in order to protect the integrity of the study.

The Faculty of Medicine and University Hospital, as well as the Researcher, will be responsible for safeguarding the information in accordance with local regulations.

You have the right to request a written summary of your medical record from the doctor.

Personal information about your health and your treatment in the study may be processed or transferred to third parties in other countries for research purposes (ensuring that their regulations comply with the minimum requirements of the Federal Law on the Protection of Personal Data Held by Individuals to always protect your privacy and confidentiality) and for security reporting, including local regulatory agencies (Secretary of Health SSA through COFEPRIS), as well as the Research Ethics Committee and the Research Committee of our Institution.

For the purposes of this study, health authorities such as the Secretary of Health and the Research Ethics Committee and/or the Research Committee of our Institution, may inspect your clinical record, including data that was collected before the start of your participation, which may include your name, address or other personal information.

If necessary, these audits or inspections may involve making photocopies of part or all of your medical record. This is to ensure that the study is being conducted properly and to safeguard your rights as a research participant.

The results of this research study may be presented at meetings or in publications.

Your anonymized personal data and the information collected will be stored and may be used for the purposes of this research for a period of 10 years, starting from the completion of the original study. After this

period, the information will be securely deleted or destroyed to ensure that it cannot be recovered. This data may be used for other studies in the future, provided that such studies are related to the same line of research (evaluation of congestion and ultrafiltration in nephrology) and on the condition that you have given your explicit consent for this storage and use by signing this document. At all times, it will be guaranteed that this data does not include information that directly identifies you, strictly maintaining your anonymity.

By signing this document, you authorize the use and disclosure of the information about your health status and treatment identified in this consent form for the purposes described. You will not lose any of your legal rights as a research participant. If there are any significant changes in how your information is used, your research physician will inform you promptly.

17.- IF YOU HAVE QUESTIONS OR CONCERNS ABOUT THIS RESEARCH STUDY, WHO CAN YOU CALL?

If you have any questions related to your rights as a research participant at the Faculty of Medicine and University Hospital, you can contact **Dr. Óscar de la Garza Castro,** president of the Research Ethics Committee of our Institution, or **Mr. Jaime Iván Aponte Vázquez** if you have any questions regarding your rights as a patient.

Research Ethics Committee of the "Dr. José Eleuterio González" University Hospital.
Francisco I. Madero Avenue and Gonzalitos Avenue s/n
Col. Mitras Centro, Monterrey, Nuevo León, Mexico.
CP 64460
Telephone numbers : 8183294050 ext. 2870 to 2874
Email: investigacionclinica@meduanl.com

CONSENT SUMMARY

TO BE COMPLETED BY THE RESEARCH PARTICIPANT

- ☐ My participation is entirely voluntary.
- ☐ I confirm that I have read and understood this document and the information provided in the study.
- ☐ I confirm that the study has been explained to me, that I have had the opportunity to ask questions, and that I have been given sufficient time to decide whether to participate. I know who to contact if I have further questions.
- ☐ I understand that sections of my medical notes will be reviewed when appropriate by the Research Ethics Committee or any other regulatory authority to protect my participation in the study.
- ☐ I agree that my personal data may be stored under codes that allow my identification.
- ☐ I agree that my primary care physician may be informed of my participation in this study.
- ☐ I agree that information about this study and the results of any examination or procedure may be included in my medical record.
- ☐ I confirm that I have been given a duplicate of this signed consent document.

CONSENT FOR OPTIONAL STUDIES/PROCEDURES		
OPTIONAL STUDY/PROCEDURE	Decision	Participant's signature
Storage and use of the information collected for future studies	☐ Yes, I accept ☐ No, I don't accept	

_____ ____ _____
Name of Research Participant Signature

_____
Date

_____ ____ _____
Name of Legal Representative (if applicable) Signature

_____
Date

FIRST WITNESS

_____ _____
Name of First Witness Signature

_____
Address

_____ _____
Date Relationship with Research Participant

SECOND WITNESS

_____ _____
Name of Second Witness Signature

_____
Address

_____ _____
Date Relationship with Research Participant

PERSON WHO OBTAINS CONSENT

I have discussed the above and clarified any doubts. To the best of my knowledge and belief, the participant is providing their consent both voluntarily and in an informed manner, and they possess the legal right and sufficient mental capacity to grant this consent.

_____ _____
Name of the Person Obtaining Consent Signature

_____
Date