# MECHANISMS AND PHENOTYPES OF HYPERTENSION IN PATIENTS IN CHRONIC HEMODIALYSIS

# NCT06764277

# DATE: 09/11/2025

# INFORMED CONSENT FORM

INSTITUTO NACIONAL DE CIENCIAS MEDICAS Y NUTRICION SALVADOR ZUBIRAN

# INFORMED CONSENT FOR PARTICIPATING IN THE RESEARCH PROJECT

## Mechanisms and Phenotypes of Hypertension in Patients in Chronic Hemodialysis
## Clinical Trials.gov Protocol NCT06764277

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**Location of the study:** Department of Nephrology and Mineral Metabolism, Chronic Dialysis Unit, Instituto Nacional de Ciencias Médicas y Nutrición "Salvador Zubirán"**.**
**Address of supporting institution:** Vasco de Quiroga No 15, Colonia Belisario Domínguez Sección XVI, Delegación Tlalpan, México, D.F.

**INTRODUCTION:**

This document is an invitation to participate in a research project of the institution. Please take all the time you need to read this document and ask the investigator to clarify any doubts you have.

You have the right to decide if you want to participate as a subject of research in this project. The investigator must explain to you the benefits and risks **without any pressure and you will have al the time you require to think, by yourself or with anyone you decide to consult, before deciding if you accept to participate.** Whatever your decision may be, it will have no effect over the medical care you will receive in the institution,

In order for you to take a truly informed decision about accepting or not to participate in this study you need to have sufficient knowledge about the possible health risks and benefits of your participation. This document will give you detailed information about the investigation, which you are free to comment with anyone you desire, for example, a family member, your personal physician, the principal investigator of the study or any member of the research team. Once read and understood the information you will be invited to be part of the project and if you accept without any pressure or intimidation, you will be invited to sign this informed consent.

This informed consent is made in accordance with the requisites established in Regulation of the General Health Law in the subject of Investigation for Health, the Helsinki Declaration and the Good Clinical Practice guidelines of the National Bioethical Commission.

At the end of the informed consent procedure, you should understand the following aspects: .

I. The justification and the aims of the investigation.
II. The procedures that will be used and their purpose, including the identification that they are

experimental procedures.

III. The risks and the inconveniences involved.
IV. The potential benefits.
V. The alternative procedures that may be to your advantage.
VI. The warranty to receive answers to your questions and clarification of any doubts on the procedures, risks, benefits, and other aspects related to investigation and the area of investigation and its treatment.
VII. You are free to withdraw you consent at any time and cease your participation in the study and this decision will not have any effect your medical care and treatment in the institution.
VIII. You should be sure that you will not be identified in a specific form and your private information will be confidential.
IX. The investigator will give you the up-to-date information obtained during the study, even this information could affect your disposition to continue to participate in the study.
X. You are assured to have the medical treatment and compensation that you are entitled to have if there are damages caused directly for the investigation.

**You can ask for more time, or to take home this document, before making a final decision in in future days.**

**INVITATION TO PARTICIPATE AS A SUBJECT OF INVESTIGATION IN THE PROJECT**

Mechanisms and Phenotypes of Hypertension in Patients in Chronic Hemodialysis

Clinical Trials.gov Protocol NCT06764277

Dear Mr., Miss, Mrs. _____

The Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (INCMNSZ), through the research group, invites you to participate as a subject of an investigation **directed to study the relation between water overload, the renin-angiotensin system and inflammatory reactivity in the hypertension and its phenotypes in chronic hemodialysis patients.**

The study will be done by evaluations immediately after and before two successive dialysis sessions in addition to a study of ambulatory blood pressure in the interval between dialysis. There will be no alteration in the date or the hours of hemodialysis treatments. We anticipate number of participants will be 50 patients. You have been invited to participate because the study will evaluate patients in renal replacement therapy with chronic hemodialysis

**STUDY PROCEDURES**

The study will not cause any change of treatment or additional treatments to you present treatment.

Your participation in the study consists in:

1. To present yourself to the hemodialysis sessions that you already have programmed.
2. In the interval between 2 dialysis there will be an ambulatory monitoring and registration of blood pressure (ABPM) with the use of an equipment that will be given to you after the first hemodialysis. You will have to bring back the equipment to the dialysis unit when you come for the next dialysis.
    - The equipment for the ABPM consists of a cuff and a registration device that records

the obtained data.

- The cuff is designed to inflate periodically and will be programmed to inflate every 30 minutes during the day and every hour during the night during a period of 24 hours
- After inflation the cuff will deflate little by little and register the blood pressure at the intervals previously mentioned
- The recording device will store the results
- During the time of ABPM you should continue with normal day activities.
- You should keep a record of the time of your daily activities that could modify the blood pressure, for example physical activity, moments of stress, and the time when you go to sleep and wake up the next day. The blood pressure record will be analyzed in the context of your activities
- The equipment you will be carrying are automatic, of light weight and silent and use the oscilometric method for measuring blood pressure.
- The ABPM equipment will be removed by us when you come to the next dialysis

3. The day you come for dialysis blood samples will be taken for the determination of concentrations of various markers of hormonal systems and inflammation related to blood pressure. The total amount of blood that will be used will be 10 ml.
4. The additional studies will be done by ultrasound techniques you are familiar with because they are used in studies of heart function and bioimpedance done routinely at your evaluation in the chronic hemodialysis program.

The research studies do not include experimental interventions of any kind. Your treatments will not be modified.

The responsibilities of the participants are to be present in the programed hemodialysis treatment and do the ABPM in the one (1) opportunity in the selected interval between dialysis and bring back the ABPM equipment at the next dialysis.
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**RISKS AND INCONVENIENCES**

The General Law of Health in the subject of Investigation in Health states that the obtention of biological samples represent a minimal risk within investigation. In your case, blood sampling is not an additional risk because the samples will be obtained from the same place and at the same time that normally are taken the samples for tests done at the beginning of hemodialysis

Potential inconveniences of the ABPM could be derived from the repeated inflation of the cuff and a relative limitation of physical activities and difficulties in peaceful sleeping. The ABPM is a safe procedure without risks derived from its use.

The information about your identity and medical information will be protected by codification of the samples and will not be revealed at any time as required by law and, therefore, you have no risk derived from loss of confidentiality.

**POTENTIAL BENEFITS**

The study is not designed to benefit you directly.
There may be results of ABPM and some of the tests that may uncover important mechanisms of hypertension.

**ECONOMIC CONSIDERATIONS**

The studies will have no cost for the patient. se le and there will no be any payment for participation.

**COMPENSATION**

If there is any complication directly related to the participation in the study the institution will provide immediate treatment and, if indicated, referral to the appropriate medical specialist.

**ALTERNATIVES TO YOUR PARTICIPATION**

Your participation is voluntary. If you decide not to participate you will continue to receive the treatment of your disease.

**COMMERCIAL PRODUCTS DERIVED FROM THE STUDY**

Any material of commercial interest derived from the study will be property of the INCMNSZ

You can ask for your results of the study after its completion to Bernardo Rodríguez Iturbe, or to Dr. José Ricardo Correa Rotter. Please remember that research is long and complex process and we cannot predict when definite results may be expected.

**IF YOU DECIDE TO STOP YOUR PARTICIPATION IN THE STUDY** The procedure is to notify your decision the investigator(s) and if you desire that your data be retired and the samples destroyed you can ask for it in writing.

**YOU MAY BE EXCLUDED FROM THE STUDY** if you miss appointments or do not perform the ABPM or other programmed studies.

**CONFIDENTIALITY IN HANDLING YOUR PERSONAL DATA**

Your name will not be used in any of the public reports of the study. All your samples will be handled with codes to avoid possible identification. Is possible that your biological samples may be used in other research projects but if this possibility arises, the decision will made by the ethical committee**,**

Your biological samples will be stored for up to 5 years.

The ethical committee of the INCMNSZ approved this study. In the future if we identify information that we consider of important for your health we will consult with the Ethics Committee on the best way to make this information available to you and your personal physician

The scientific data obtained as part of the study would be used in medical publications and congress.
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**IDENTIFICATION OF THE INVESTIGATORS*.***

If you need to clarify doubts regarding the study please contact any one of the following:
+52.19991490061 (Dr. Rodríguez-Iturbe), +52.15579597066 (Ricardo Correa-Rotter),
+52.5518437638, (Dr. Eduardo Ríos Argaiz)

I you have questions regarding your rights as participant of the study please contact the President of the Ethics of Investigation Committee of the INCMNSZ **(**Dr. Arturo Galindo Fraga, telephone: 54870900 ext. 6101).

## DECLARATION OF INFORMED CONSENT

I have carefully read this informed consent document; have made all the questions I wanted and they have been answered to my satisfaction. In order to participate in the study, I make known that the general and specific purposes of recruitment and the possible injury and inconveniences of the study have been explained to me at my complete satisfaction.

I agree to voluntarily donate mis biological samples (urine and blood) to be used for the study. In addition, all my medical and biological information could be used in the study for the purposes of the study.

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I agree, in case is necessary, to be contacted in the future if the study if the study requires the collection of additional information that is relevant for my health.

My signature indicates that I have received a duplicate of this consent form.

Please answer the following questions:

| | | YES | NO |
|---|---|---|---|
| a. | Have you read and understood the informed consent form in your own language? | ☐ | ☐ |
| b. | Have you had the opportunity to ask questions and discuss the study? | ☐ | ☐ |
| c. | Have you received satisfactory answers to all your questions? | ☐ | ☐ |
| d. | Have you received sufficient information and had enough time to make a decision? | ☐ | ☐ |
| e. | Do you understand that your participation is voluntary and you are free to cancel your participation in the study at any time without having to justify your decision without your decision affecting your medical attention or loss of benefits that you may be otherwise entitled ? | ☐ | ☐ |
| f. | Do you authorize access to your medical information to principal investigator or his/her representatives, auditors and regulatory committees and Mexican government instances that regulate the study? | ☐ | ☐ |
| g. | Do you understand the potential risks, some of them unknown, to participate in the study? | ☐ | ☐ |
| h. | Do you understand that you may not receive any direct benefit for your participation in the study? | ☐ | ☐ |

| | | YES | NO |
|---|---|---|---|
| i. | Have you discussed other potential treatment options and understand that these options are available to you? | ☐ | ☐ |
| j. | ¿Entiende que no está renunciando a ninguno de sus derechos legales a los que es acreedor de otra forma como sujeto en un estudio de investigación? (NOT APPLICABLE) | ☐ | ☐ |
| k. | Do you understand that investigators may take you out of the study without your consent because you did not followed the requirements and also your personal physician if he considers that your retirement is to your best interest?? | ☐ | ☐ |
| l. | Do you understand that the institution and sponsors may stop the study at any time? | ☐ | ☐ |
| m. | Do you understand that you will receive an original signed copy of the consent form for your personal file? | ☐ | ☐ |

**Declaration of the patient:**

I, _____ declare that is my decision to participate in the study My participation is voluntary.

I have been informed that I can refuse to participate or cease my participation at any time without any penalty or loss of benefits. If I stop mi participation, I will nevertheless receive the treatment that I have a right to receive in the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán (INCMNSZ). I may ask for additional information about risks and benefits of the study and obtain the results of my clinical tests if I ask for them. To ask any questions of information concerning the study may be obtained from Bernardo Rodríguez Iturbe (+52.19991490061), Ricardo Correa Rotter (+52.15579597066) o Eduardo Ríos Argaiz (+52.5518437638)

I have to inform the investigators of any change in my health or medications or change of address that make take place, as soon as possible.

I have read and understood all the information I received related to mi participation in the study. I had the opportunity to discuss and ask questions about the study and they have been answered to my satisfaction.

I have been informed that if I have further questions about the study and my rights, I am at liberty to contact the President of the Committee of Research of the INCMNSZ Dr. Arturo Galindo Fraga, (Tel. 54870900 ext. 6101).

_____ _____

Name of the Participant Signature of the Participant

_____

Date

_____

Place digital mark of the participant here if he/she does not know how to write

_____ _____

Name of the legal representative (if applicable) Signature

_____

Date

_____ _____

Name of investigator that explained this document Signature

_____

Date

_____ _____

Name of witness 1 Signature of Witness 1

_____ _____

Date Relation with participant

Address: _____

_____

_____ _____

Name of witness 2 Signature of Witness 2

_____ _____

Date Relation with participant

Address _____

_____

Place and Date :

_____