Official Study Title: PHASE III, RANDOMIZED, ACTIVE-COMPARATOR CONTROLLED CLINICAL TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF NIFEDIPINE 30MG EXTENDED-RELEASE IN ADULT PATIENTS DIAGNOSED WITH MILD OR MODERATE HYPERTENSION IN COLOMBIA.

Protocol Number: NIF30-0120
Document: Informed Consent Form (ICF) – Colombia
ICF Version: 5.0
Document Date: 23-Aug-2023
NCT Number: To be confirmed

Date: 26th february 2026

Dear ClinicalTrials.gov Registration Team,

Please find attached the Informed Consent Form (ICF) for Colombia corresponding to Protocol NIF30-0120, Version 5.0, dated 23-Aug-2023, submitted for registration purposes.

The NCT number is currently pending confirmation and will be provided once available.

Please let me know if any additional documentation or clarification is required.

Sincerely

Trinidad Plata B
MSL Laboratorios Richmond Colombia
tplata@richmondlab.com

PHASE III, RANDOMIZED, ACTIVE-COMPARATOR CONTROLLED CLINICAL TRIAL TO EVALUATE THE EFFICACY AND SAFETY OF 30MG EXTENDED-RELEASE NIFEDIPINE IN ADULT PATIENTS DIAGNOSED WITH MILD OR MODERATE ARTERIAL HYPERTENSION IN COLOMBIA.

Informed Consent Form
Protocol NIF30-0120

Version 5.0 - 08-23-2023
Colombia

Name of Principal Investigator:	Paula Marcela Ochoa Castañeda
Institution/Research Center:	Center for Medical Care and Research — CAIMED S.A.S
Address of the research center of research:	Carrera 4 este # 24 — 65, Floor 2. Chía, Cundinamarca
Phone number during business hours:	601 8707070
24-hour contact number:	•s7 317 5131016

- You are invited to participate in this research study. You are free to decide whether you want to take part in the study. This document will help you make a more informed decision about your participation.
- Remember that once you participate, you are free to withdraw from the study at any time, and keep in mind that if you decide not to participate in the study, your medical care will not change in any way.
- Remember that by agreeing to participate, you also agree to allow the study sponsor,
- LABORATORIOS RICHMOND COLOMBIA S.A.S., to use and share information about your health.
- We appreciate you taking the time you need to make a decision. Please feel free to ask any questions you may have to the staff who gave you this document or to the study doctor.
- If you decide to participate, you will be asked to voluntarily sign and date this informed consent form before any study-related procedures are performed. You will receive a copy of the informed consent form to keep for your records.

The study presented is funded by a company called LABORATORIOS RICHMOND COLOMBIA S.A.S., which will pay the Center for Medical Care and Research (CAIMED) for conducting this study.

1. What is the purpose of this study?

The purpose of this study is to evaluate whether the study drug, Richmond's Nifedipine 30mg Extended Release, compared to the same drug, Nifedipine 30mg Extended Release, but from another laboratory that is currently registered in Colombia, controls blood pressure in the same way, that is, is effective in the treatment of high blood pressure.

Nifedipine is one of the drugs currently used to treat high blood pressure and is usually administered in combination with other antihypertensive drugs. The drug Nifedipine 30mg Extended Release, produced by Richmond Laboratories, has been marketed in Colombia for 10 years and is currently undergoing a registration renewal process.

2. What medication will I receive?

You will be randomly assigned to a group to decide which type of study medication you will receive.
you will receive:

Group A:

Eight (8) weeks of treatment with Nifedipine Richmond, new formulation as sole treatment or in combination with another antihypertensive drug depending on your current treatment (no changes will be made to the combinations of drugs you use for hypertension). Subsequently, from week 9 to week 19 (10 weeks), you will receive extended-release Nifedipine, currently registered in Colombia, as the sole treatment or in combination with another antihypertensive drug, depending on your current treatment regimen. It is important to note that the information obtained during weeks 9 and 10 will not be taken into account for the analysis (statistical silence) as this time must be allowed for the complete elimination of the first medication (washout period).

Group B:

Eight (8) weeks of treatment with extended-release Nifedipine, currently registered in Colombia, as the sole treatment or in combination with another antihypertensive drug, depending on your treatment regimen. Subsequently, from week 9 to week 19 (10 weeks), you will receive Nifedipine Richmond New formulation as the sole treatment or in combination with another antihypertensive drug, depending on your current treatment regimen. It is important to note that the information obtained during weeks 9 and 10 will not be taken into account for the analysis (statistical silence) as this time must be allowed for the complete elimination of the first medication (washout period).

The product nifedipine, which has similar manufacturing characteristics and a valid INVIMA health registration, will be used as a comparator.

You have a 50-50 chance of being assigned to Group A or Group B.

The study medications will be provided in capsules to be taken orally. Administration of the medication by any other route is not being considered.

You will receive the medication Nifedipine Richmond New Formulation and Nifedipine Extended Release, both currently registered in Colombia, on an alternating basis. Each will be taken for a period of 8 weeks, for a total of 16 weeks between the two medications.

Neither you nor the study doctor will know which of the two medications you are receiving. In the event of a health emergency, the doctor will be able to obtain this information so that you can receive the necessary care.

3. Who can participate?

You can participate in the study if, in addition to being of legal age, your doctor has diagnosed you with primary hypertension with blood pressure control during the last 4 weeks of inclusion, verified by medical history, according to ESC/ESH guidelines. This information will be verified in your medical history.

Additionally, in order to participate in this study, you must:

- Be receiving therapeutic management for your high blood pressure with nifedipine alone or in combination with other antihypertensive drugs, according to the criteria of your treating physician
- Be able to read, understand, and complete the questionnaires provided to you during the study
- Voluntarily agree to participate in this study

If there are reasons why you cannot participate in the study, the study staff or physician will inform you.

Approximately 50 people will participate in the study.

4. How long will I remain in the study?

You will remain in the study for a total period of 20 weeks, i.e., 18 weeks of treatment as indicated in the description of groups A and B (section 2 of this document) and two additional weeks, during which you will be scheduled for a final visit to conclude your participation. The doctor or study staff will tell you when to come to the office and give you additional recommendations to follow during your participation in the study.

5. What happens during study visits?

The doctor or study staff may perform any or all of the following procedures:

- Give you the study medication and provide detailed instructions on how to take it
- You will receive a Patient Identification Card. This pocket-sized card is intended for healthcare professionals and contains important information about this study as well as contact information to use in case of emergency. Please carry this card with you at all times and show it whenever you consult a healthcare professional.
- Assess you clinically to detect changes in blood pressure readings
- Review your health history, including details about your antihypertensive management, and ask you how you feel.
- Review any previous medications you have taken and those you are currently taking.
- Review your study medication diary
- Perform a physical exam that includes vital signs.
- Perform electrocardiograms (ECG) to monitor your heart's electrical activity.
- Blood and urine samples will be taken. These samples will be used to perform: complete blood count (CBC), hepatitis B surface antigen, kidney and liver function tests, T4L and TSH, blood sugar, sodium, potassium, chloride, and pregnancy test.
- You will be asked to complete questionnaires or logbooks of your blood pressure readings to verify the management of your hypertension and your medication intake.

The study visits will take place at the Medical Care and Research Center (CAIMED) facilities, as instructed by the study physician. These visits will be as follows: initial visit (week 1), visit one (week 5), visit two (week 9), visit three (week 11), visit four (week 15), visit five (week 19), closing visit (week 20).

A **screening visit** will be conducted to verify that you are eligible to participate in the study. The study will be presented to you, and you will then be asked to complete the informed consent form. An initial assessment will be conducted by a family physician, and your initial conditions upon entry into the study will be recorded (collection of medical information and vital signs).

- Laboratory tests will be performed during screening week, week one week five, week nine, week eleven, week fifteen, and week nineteen

Additionally, during subsequent visits, educational materials and documents will be provided, in which you will be asked to record your blood pressure readings and information related to your disease and medical management. During the **initial visit** (Week 1), the randomization process will be carried out, through which you will be assigned to group A or group B of the study. Based on this assignment, you will be given the medication and instructions for its use.

6. Will **genetic analyses** be performed **on** the blood and urine samples obtained?

No genetic analysis will be performed, as this is not the objective of the study. Please also note that your samples will only be used for the purposes of this study and will therefore not be stored; in other words, once processed, they will be discarded.

7. What do I need to do on my own?

- Take the study medications as directed, which means taking the medication at the same time every day. They should not be chewed, crushed, or split; they should preferably be taken with water and on an empty stomach.
- Record the number of tablets or capsules of the study medication you take during the study treatment period in the study medication diary.
- Attend the scheduled follow-up visits (seven in total).
- With the help of the blood pressure monitor that will be provided to you by the study staff and the recording material, you will be asked to take your blood pressure readings daily and record them, following the recommendations given.
- If you miss/forget a dose of medication, despite reminder strategies, take the missed dose as soon as possible on the same day. If more than 12 hours have passed since the scheduled time, wait until the next dose. For this next dose, take the medication as usual. No

You should not take extra medicine to make up for a missed dose. You should store the medicine in its original container and packaging at a temperature below 30°C.

8. How might the study tests make me feel?

You may feel discomfort during some of these tests or experience some discomfort. Some tests may also present risks such as the following:

Blood samples: Having blood drawn from your arm may cause pain, bruising, dizziness, and rarely, infection.

Performing an **electrocardiogram (ECG)** may cause minimal discomfort during the placement and removal of the ECG electrodes from your skin.

9. What should I know about the study drug and side effects?

Side effects in healthy **people**. The following are the most common side effects reported by healthy people who have taken Nifedipine:

- Feeling dizzy
- Generalized edema
- Headache
- Nausea
- Heartburn
- Redness

The following side effects have been reported less frequently by healthy individuals who have taken Nifedipine:

- Cough
- Shortness of breath
- Palpitations
- Hives
- Constipation
- Chest pain
- Itching
- Muscle cramps
- Mood swings
- Feeling nervous

Side effects ranged from mild to severe.

With any medication, there is a possibility of an allergic reaction. The most commonly reported symptoms associated with allergic reactions are:

- Rash
- Cough
- Dizziness
- Fainting
- Hives

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- Itching
- Chest tightness
- Shortness of breath
- Wheezing

10. What serious side effects could the study drugs cause?

The following side effects have been observed in people who have taken Nifedipine. These listed effects may occur when taking Nifedipine orally at the indicated doses, but they occur very rarely.

Serious effects:

- Cardiovascular: myocardial infarction (up to 4%), ventricular arrhythmia (less than 0.5%)
- Gastrointestinal: gastrointestinal obstruction, gastrointestinal ulcer
- Hematological: aplastic anemia

The various tests and samples that will be taken during the study will allow us to monitor your health and identify any changes that could be associated with these secondary events so that the necessary actions can be taken.

11. Are there any other risks?

Other dermatological side effects have been reported, such as Stevens-Johnson syndrome and erythema multiforme (each less than 1 case per 1 million prescriptions). hepatological side effects include transient and generally clinically insignificant increases in laboratory results during treatment (in less than 1% of patients), and ophthalmological side effects include blurred or abnormal vision (in less than 2% of patients). Your doctor or study staff can discuss these with you.

12. Can I participate in the study if I am pregnant?

If you are pregnant, trying to become pregnant, planning to donate eggs, or breastfeeding, you cannot participate in the study.

If you are capable of becoming pregnant, you must use a reliable method of contraception during the study and for a period of 90 days. This will be discussed with you. The following methods of contraception are permitted during the study:

- Progesterone-only implant
- Hormone-releasing intrauterine system (IUS)
- Intrauterine device (IUD)
- Bilateral tubal occlusion (tubal ligation)
- Vasectomy of the male partner
- Abstinence (no sexual intercourse)

If you become pregnant during the study, you must notify the study doctor immediately. Becoming pregnant during the study is considered a serious adverse event because the adverse effects of the medication during breastfeeding are unknown.

pregnancy. This is why, if you become pregnant, you will stop receiving the study medication and your pregnancy will be monitored.

There may be risks if you are a man and your partner is pregnant or trying to become pregnant. If you are a man and your partner could become pregnant, and you and your partner are not willing to abstain completely (not have sex), you and your partner must use a reliable method of contraception during the study and for a period of 90 days or longer after the last dose of study medication. This will be discussed with you. A male condom may be used in addition to one of the contraceptive methods listed above.

If your partner becomes pregnant during the study, you must inform the study doctor immediately. Your partner's pregnancy will be monitored, after signing an informed consent form for this purpose. You must also agree not to donate sperm during the study and for 90 days after your last dose of the study medication.

13. Will I benefit from participating in the study?

You will not directly benefit from participating in the study other than through regular medical checkups, information and education about hypertension, and other wellness activities that will be offered during the study period, such as workshops on nutrition, healthy habits and cooking, and physical activity.

On the other hand, the information obtained from the study could help other people with the same disease in the future.

14. What happens if new information comes to light after I join the study?

You will be notified in a timely manner of any new information that could affect your participation in the study.

15. What happens if I am injured in the study?

If you are injured as a direct result of the study medication or a study procedure, the Sponsor will pay the reasonable costs of medical treatment required for the injury.

The sponsor will not provide any other form of compensation. You are not asked to release or waive any of your legal rights with the institution, the researcher, or the Sponsor for liability or negligence.

Any adverse event, injury, or side effect, whether known or unknown, that occurs as a direct result of the medication (investigational product or comparator) or study procedures will be covered by the Sponsor through the policy established between LABORATORIOS RICHMOND COLOMBIA S.A.S. and the insurance company CORRECOL, which will provide permanent coverage during the study and in the event of an adverse event, injury, or side effect after the study has ended. The policy will be renewed periodically, and each time this occurs, the investigator will inform you of the new policy number and its validity period.

If you believe you have experienced an adverse event, injury, or side effect as a direct result of or the study procedures, please contact the

investigator (see contact details at the end of this consent form) or the staff at the research center where the study is being conducted, who will explain the internal procedure for handling adverse events.

16. Will I be paid?

The institution will provide transportation and meals for visits that require them. You will not receive any financial compensation other than the aforementioned assistance.

17. Will I have to pay?

Some of the treatments or tests used in this study may be part of your routine medical care to maintain your health, even if you do not participate in this study. You or your insurance company may be responsible for the cost. All study medication and study-related tests will be provided to you at no charge.

18. What happens if I want to leave the study or stop taking the study medication?

If you are thinking about leaving, you should tell the study doctor. The study doctor can help you with your decision. If you decide to leave, you will not be penalized, and you will not lose any benefits you had before starting the study.

If you decide to stop taking the study drug, tell your doctor or study staff so you can do so safely. You can remain in the study, even if you stop taking the study drug, by providing information or participating in study procedures. Your study doctor can explain this to you.

The study doctor or staff may contact you to ask about your health.

19. Can I be withdrawn from the study?

There may be several reasons why you might be withdrawn from the study. For example, you may need another treatment, have health problems that require you to leave the study, or not be able to follow the study instructions, or the study may be terminated. Likewise, there may be a change in the study that could end your participation, for the study being terminated by the sponsoring laboratory. The reason will be explained by the study doctor.

20. Will my privacy be protected? Who has access to my data?

The study doctor and research team will use your health data (e.g., name, address, medical history, and sample data) to carry out this study, as described in this consent document.

Health data is entered into the Sponsor's system with a numeric code, which is that is, the study physician will replace your name and other general information about

you, except for your age or date of birth and gender, with a special code that identifies you. The Sponsor does not have a key that can link the data to your personally identifiable information.

Being in the study means that the study team allows the following parties to view your coded health data to ensure that the study is conducted correctly:

- Government agencies around the world
- Ethics committees that oversee research
- Sponsor representatives (monitors and auditors)
- Researchers involved in the research you are participating in
- Insurance company (in the event of a claim for injury arising from participation in the study)

It is the responsibility of the study physician and study staff to ensure that the health data (as described above) sent to the Sponsor (previously coded) does not identify you. Instead, it may include a code consisting of letters that do not allow you to be identified and dates of study visits.

You will not be identified by name in any reports published about this study or in any other scientific publication or presentation.

If you believe you have suffered an injury as a result of participating in the study, the study team may also share your health data with the Sponsor's insurance company to resolve your claim.

The Sponsor may use the health data sent to them:

- To see if the study drug works and is safe;
- To compare the study drug with other drugs;
- To develop new tests (related to the disease under study or related diseases or the study drug)
- To apply for approvals from the relevant authorities in relation to the study drug;
- To allow external researchers to use clinical data that identifies you.

The Sponsor may share your coded information with research partners and service providers who assist in conducting the study and analyzing the results. Study data may also be shared with regulatory authorities and joint review boards appointed by the research team and Richmond Laboratories.

You expressly authorize that your encrypted information (without identification number) be transmitted, transferred, and/or shared with companies affiliated with or subordinate to the Sponsor's parent company. The encrypted information may be known by companies that are part of the Sponsor's corporate group.) be transmitted, transferred, and/or shared with affiliated companies subordinate to the Sponsor's parent company. The encrypted information may be known to companies belonging to the same business group as Laboratorios Richmond, together with the

individuals, companies, and regulatory bodies with which it works, which may be located in other countries around the world, including Argentina.

In compliance with the provisions of Law 1581 of 2012 (Data Protection Law), the Sponsor maintains strict measures and policies to safeguard the confidentiality and processing of personal data provided by you as the Data Subject.

Your permission to use and share your health data will be valid for the terms established by Colombian law on this matter and/or by the Sponsor's policy related to personal data privacy, whichever is stricter.

You may withdraw your permission to use and share your health data at any time by contacting the study physician. If you do so, you will not be able to remain in this study.

No new health data that identifies you will be collected after that date.

However, health data that has been collected may still be used to maintain the integrity of the study and its results as required by clinical trial rules. You have the right to agree to such use, within the limits of the law. You may, under the terms established by law, contact the study physician to ask the Sponsor to exercise the rights enshrined in the applicable regulations and, in particular, the following rights regarding the processing of your data:
(i) Access your data (update, modify, delete, and correct it); (ii) Request its removal.

You may not be able to review some of your study-related records until the study is complete. When the study is complete, you may contact the study doctor to view the study health data and correct any errors.

21. Will information about the study be included in a Registry Data Bank†

A description of this clinical study will be available at https://eudract.ema.europa.e. This website will not include any information that could identify you. At most, the website will include a summary of the results. You can search on this website at any time.

22. Where can I get more information?

- **If you have any questions about the study, please contact us at any time.**

a:

Function	Name	Phone
Principal Investigator	Dr. Paula Marcela Ochoa Castañeda	Telephone during business hours: 24-hour contact number: 3175131016

- In the event of an injury related to the research, please contact:

Position	Name	Phone

Principal Investigator	Dr. Paula Marcela Ochoa Castañeda Phone number during business hours: 24-hour contact number: 3175131016

- If you have questions regarding your rights, please contact:

Position	Name	Phone number	Email
Ethics Committee	Ethics Committee in Research VITA	3503189822,	comitedeeticavita@caimed.com

23. Signature pages

I have read this document and its contents have been explained to me. I understand the purpose and what will happen to me in this study. I freely give my consent to join this study, as described in this document.

I understand that I will receive a copy of this signed document.

By signing this consent form, I authorize the use, access, and sharing of my Personal Data as described in this document.

This consent is valid unless and until revoked.

NOTE: THE SIGNATURE, DATE, AND TIME MUST BE COMPLETED ONLY BY THE VOLUNTEER OR THEIR DESIGNATED REPRESENTATIVE

Name of Volunteer

Volunteer's Signature

ID Number

AM

PM

Time | Minutes

Time of Signature

Day | Month | Year

Date of Signature

NOTE: THE INFORMATION BELOW MUST BE COMPLETED BY EACH WITNESS ONLY.

With my signature, I certify that all questions were satisfactorily answered to the volunteer and that their participation is voluntary.

Witness Name

Witness Signature

ID Number

Relationship to the volunteer

Date | Month | Year

Date of Signature

Dirección

NOTE: THE INFORMATION BELOW MUST BE COMPLETED BY EACH WITNESS ONLY

By signing, I certify that all questions have been satisfactorily answered for the volunteer and that their participation is voluntary.

Witness Name

Witness Signature

ID Number

Relationship to the volunteer

Date | Month | Year

Address

Signature of the Investigator administering the Consent

Day | Month | Year

In the case of an illiterate person, please place their fingerprint in this space: