OFFICIAL STUDY TITLE: Effects of Remote Ischemic Preconditioning on Contrast-Induced Nephropathy in Diabetic Patients: Relationship with Oxidative Stress and Inflammatory Status.

NCT NUMBER: PENDING ASSIGNMENT

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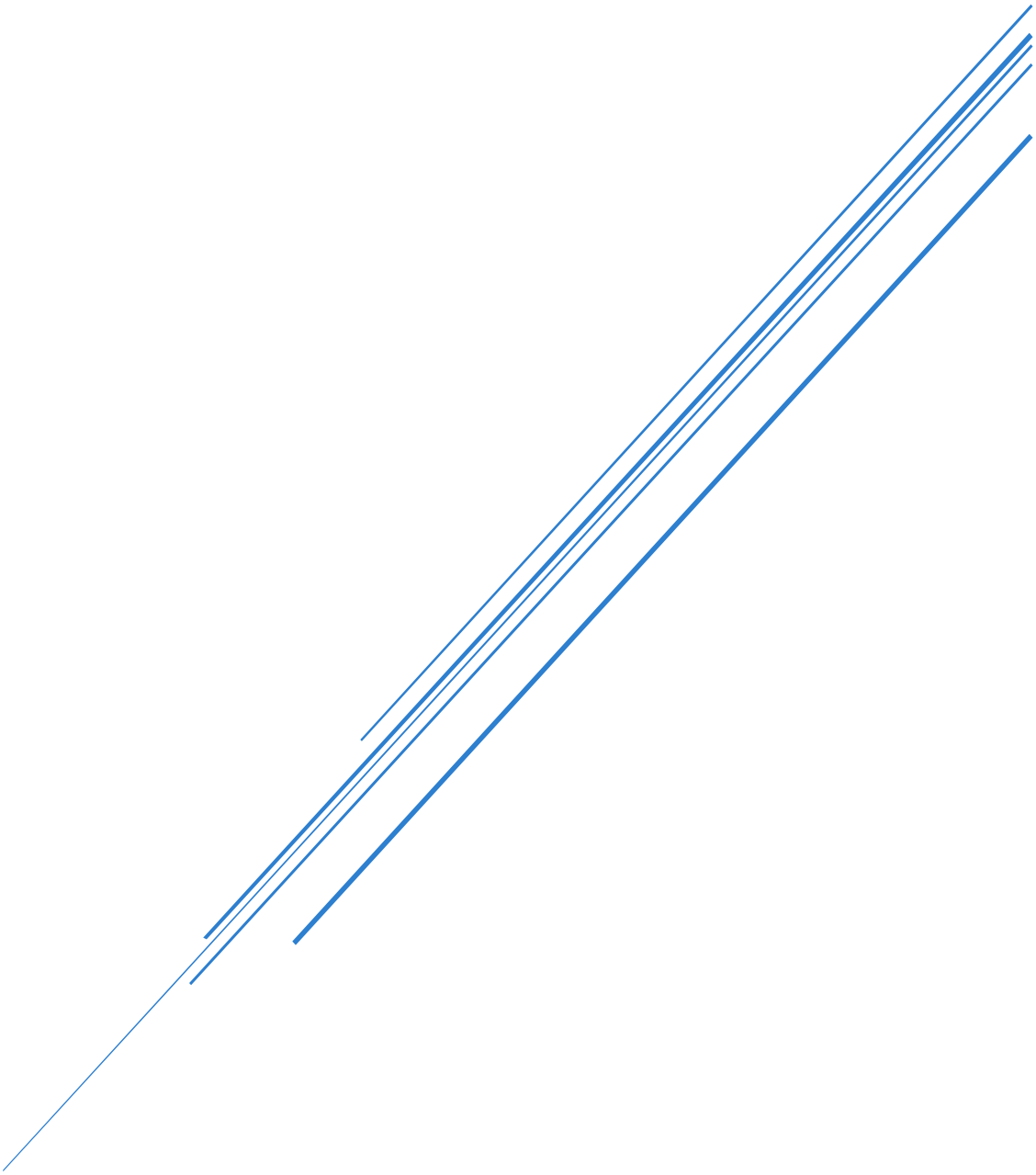

Informed Consent Form (ICF).

Study Title: Effects of Remote Ischemic Preconditioning on Contrast-Induced Nephropathy in Diabetic Patients: Relationship with Oxidative Stress and Inflammatory Status
Study Acronym: PRINCES Study

1. Introduction

You are invited to participate in a research study conducted by the Intensive Care Unit at Hospital General Universitario Santa Lucía and the Department of Human Physiology at the University of Murcia. This form provides information to help you understand the study, its risks, and benefits so you can make an informed decision.

2. Purpose of the Study

This study aims to assess whether a simple, non-invasive technique called Remote Ischemic Preconditioning (RIPC) can prevent kidney damage caused by contrast agents used during coronary angiography in patients with diabetes mellitus.

3. Background

Diabetes may lead to kidney damage, especially in patients with poor disease control or additional risk factors such as hypertension, high cholesterol, or smoking. Some diabetic patients may require procedures using intra-arterial contrast agents, which can impair kidney function, especially if the patient has pre-existing renal vulnerability.

4. Procedures

If you agree to participate, the following will occur:

- You will undergo RIPC: a blood pressure cuff will be placed on your arm and inflated 50 mmHg above your systolic pressure for 5 minutes, followed by 5 minutes of deflation. This cycle will be repeated 4 times, about 45 minutes prior to your coronary catheterization.
- Blood and urine samples will be collected at specific intervals to evaluate biomarkers related to kidney function, inflammation, and oxidative stress.

5. Voluntary Participation

Your participation is entirely voluntary. You may refuse or withdraw at any time without affecting your medical care.

6. Risks and Discomforts

RIPC is considered safe. However, minor discomfort during cuff inflation or bruising may occur. Blood sample collection involves standard procedures with minimal risks.

7. Potential Benefits

While individual benefit is not guaranteed, this study may help prevent contrast-related kidney damage. The broader goal is to improve care for diabetic patients undergoing procedures with contrast agents.

8. Confidentiality

Your data will be protected according to current data protection laws. All collected data will be identified by a code and only authorized study personnel will have access to the key linking your identity. Data may be transmitted securely for study purposes, but no personal identifiers will be included.

9. Contact Information

If you have questions or concerns, please contact:

- Dr. María Galindo Martínez (Intensive Care Unit. Hospital General Universitario Sta. Lucía. Cartagena).
- Dr. M.ª Dolores Rodríguez Mulero (Intensive Care Unit- Hospital General Universitario Sta. Lucía. Cartagena).
- Dr. Francisca Rodríguez Mulero (Department of Physiology. University of Murcia).

10. Voluntary Consent

By signing this document, you confirm that you understand the nature of the study, the risks and potential benefits, and that you consent voluntarily to participate.

Participant's Name: _____
Participant's ID Number: _____
Signature of Participant: _____ Date: _____

Investigator's Name: _____
Investigator's License Number: _____
Signature of Investigator: _____ Date: _____