STUDY CONSENTS

“Morbidity of Conventional and No-touch Saphenectomy in Coronary Artery Bypass Grafting, a Randomized Non-inferiority Clinical Trial”

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July 5th, 2024.

INFORMED CONSENT

"Morbidity of Conventional and No-touch Saphenectomy in Coronary Artery Bypass Grafting, a Randomized Non-inferiority Clinical Trial"

MD. Juan Montero, Carolina Sosa, Maximiliano Hernandez, Santiago Cubas, Gerardo Soca y Victor Dayan.
Instituto Nacional de Cirugía Cardíaca (INCC), Tel: +59824810209, cirugia@incc.com.uy.

We invite you to participate in this Research Project that aims to demonstrate the non-inferiority of the "no-touch" saphenectomy technique vs. with the conventional one. "No-touch" consists of dissecting the saphenous vein with the tissue that surrounds it, which has shown good results in the patency of bypasses in the short and long term, although a higher incidence of edema, a feeling of "heaviness" has been reported. or wound exudate before discharge, not evident after one month and no incidence of serious complications has been reported. The conventional technique consists of dissecting the saphenous vein without the tissue that surrounds it, a technique currently used.

The data obtained here will be important to begin using this new technique more frequently in patients under 70 years of age. It will be decided at random which of the two techniques will be used in each one, thus forming two groups. Then it will be monitored in person upon discharge, after a month at the polyclinic and by telephone after 6 months. After one year, a new consent will be given in which you will be offered to undergo a computed tomography angiography to assess the patency of these bypasses, data of great importance for the local surgical community.

This Research Project and this Informed Consent have been approved by the Ethics Committee of the British Hospital on March 4, 2024 by the Committee Coordinator, Dr. Manuel Baz.

Your participation will be voluntary and unpaid. We ask that you read this document carefully and ask any questions and queries you wish at this time to health personnel or people you trust. You will always have the option to withdraw whenever you want without having to give any explanation. He will be evaluated a week after surgery, a month later at the polyclinic and 6 months later by telephone.

After considering that you have the necessary information and agree to participate, you must sign this document, granting your consent to provide data. If you do not agree and do not wish to sign, there will be no damages or consequences of any kind.

Your identity and the data provided will only be known to the researchers. Your name will not be used in the investigation. Each participant will be assigned a code and will work with it. The results will be shared while maintaining the anonymity of the participants.

In the event of any wound complication such as: infection, hematoma, blisters, secretions, necrosis, wound dehiscence, paresthesia, functional impotence or pain in the surgical wound, it will be treated by the INCC staff in its polyclinic. cures without implying an economic cost for the patient.

By signing below I acknowledge that:

"I have read this document in its entirety. I have been given the opportunity to ask questions and discuss the different aspects of the Research project. I agree to provide data about myself that may be helpful to the proposed research. "I can withdraw from the research group at any time I decide."

Participant's name: _____ Signature:_____

CI:_____ Telephones: _____/_____

Researcher:_____ Researcher signature:_____

INFORMED CONSENT ANGIOTOMOGRAPHY ONE YEAR AFTER SURGERY.

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We invite you to participate in this Research Project that aims to demonstrate the non-inferiority of the "no-touch" saphenectomy technique vs. with the conventional one. Techniques that have been informed in the previous consent.

The data obtained here will be important to begin using this new technique more frequently in patients under 70 years of age. Which of the two techniques will be used in each participant will be randomly defined, thus forming two groups. You will then be contacted after a year and if you agree, you will be offered a computed tomography angiography to assess the patency of these bypasses, data of great importance for the local surgical community.

This Research Project and this Informed Consent have been approved by the Ethics Committee of the British Hospital on March 4, 2024 by the Committee Coordinator, Dr. Manuel Baz.

Your participation will be voluntary and unpaid. We ask that you read this document carefully and ask any questions and queries you wish at this time to health personnel or people you trust. You will always have the option to withdraw whenever you want without having to give any explanation. He will be evaluated a week after surgery, a month later at the polyclinic and 6 months later by telephone.

After considering that you have the necessary information and agree to participate, you must sign this document, granting your consent to carry out the study. You should know that Coronary Angiotomography is a non-invasive procedure, you should not be pregnant since you will be exposed to radiation, nor be allergic to contrast. Any other questions that arise from the procedure can be asked at any time to the treating team. If you do not agree and do not wish to sign, there will be no damages or consequences of any kind.

Your identity and the data provided will only be known to the researchers. Your name will not be used in the investigation. Each participant will be assigned a code and will work with it. The results will be shared while maintaining the anonymity of the participants.

By signing below I acknowledge that:

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Participant's name: _____ Signature:_____

CI:_____ Telephones: _____/_____

Researcher:_____ Researcher signature:_____