Patient Information Sheet and Informed Consent

Official Title of the Study:

Knee Arthroplasty Surgery: Short-Term Effects of Robotic Assistance (ROSA). Randomized Study.

Version: 3.0.

Date: March 20th, 2022

Principal Investigator: Inmaculada Neira, M.D.

Site: Hospital Universitario Santa Cristina. Madrid, Spain.

Introduction

You are being invited to take part in a research study. The study has been approved by a Research Ethics Committee and by the Spanish Agency of Medicines and Medical Devices (AEMPS), in accordance with current legislation (Royal Decree 1090/2015 of December 4 and EU Regulation 536/2014 of April 16).

Our aim is to provide you with accurate and sufficient information so you can decide whether or not to participate. Please read this information sheet carefully and ask us about any questions you may have.

Voluntary Participation

You are being invited to participate because you have been diagnosed with knee osteoarthritis and are a candidate for total knee replacement surgery (total knee arthroplasty, TKA).

Your participation is entirely voluntary. You may choose **not to participate**, or withdraw your consent at any time, without affecting your relationship with your doctor or the quality of your medical care.

Study Objective

To compare early functional recovery in patients undergoing robotic-assisted total knee arthroplasty versus conventional manual surgery during the first three months after surgery.

Study Description

Eligible participants are patients with knee osteoarthritis who are scheduled for total knee replacement using the same prosthesis model.

The surgical robot assists during TKA by guiding bone resections and evaluating soft tissue balance to optimize implant positioning. Use of the robot requires two additional small incisions in the thigh and leg to place anchoring pins (in the femur and tibia) for sensor attachment, in addition to the standard surgical incision.

The study will include a total of 60 patients. Thirty will undergo surgery with robotic assistance and thirty without. The same prosthesis and surgeon will be used for all

patients. Regardless of study participation, the same implant would be used in standard clinical practice.

Assignment to the robotic or manual group will be **random**.

Study Activities

The study will last 3 months. Follow-up visits will occur at 2–3 weeks, 2 months, and 3 months after surgery. Participation in the study will not increase the number of follow-up visits beyond what would normally occur.

Routine imaging will include X-rays and long-leg standing radiographs (TeleRx) as part of standard TKA follow-up.

In addition, due to participation in the study, patients will complete questionnaires during the preoperative visit and at 2 and 3 months post-op. A surface electromyography (EMG) will also be performed 3 months after surgery. This test involves applying two skin electrodes over the target muscle to measure muscle strength during contraction.

Timepoint	Tests/Activities
Preoperative visit	X-rays; TeleRx; Questionnaires
2–3 weeks post-op	Questionnaires
2 months post-op	X-rays; TeleRx; Questionnaires
3 months post-op	X-rays; Questionnaires; EMG

Risks and Discomfort

The ROSA surgical robot has been approved and marketed since 2019 and has been used at this hospital since January 2021.

Potential risks include infection, implant malalignment, joint instability (due to improper soft tissue balancing), or periprosthetic fracture. These are the same risks associated with conventional TKA without robotic assistance.

Discomforts from study participation include longer follow-up visits due to the additional tests. The surface EMG is non-invasive, painless, and performed during an outpatient visit.

Participant Responsibilities

- Attend scheduled visits and complete study-related activities.
- Report any adverse events to the study physician.

Potential Benefits

You may experience faster functional recovery with the robotic system, but there is no guarantee of individual health benefit from participating in this study.

Data Protection

Processing, communication, and storage of your personal data will comply with the General Data Protection Regulation (GDPR, May 25, 2018) and Spanish Law 3/2018 on Data Protection and Digital Rights.

You may exercise your rights of access, correction, objection, or erasure by contacting the study investigator.

Study data will be coded and will not include identifying personal information. Only your study physician and authorized collaborators will be able to match your data to your identity. Your identity will not be disclosed unless required for medical or legal reasons.

Identified data will only be accessible to the study physician, health authorities (e.g., AEMPS or foreign regulatory agencies), and the Ethics Committee if necessary for data verification, always maintaining confidentiality as required by law.

Data will be collected in a research file managed by the institution. It may be used for future studies related to this one. The investigator will ensure your privacy is protected and your data will not be linked to other databases that could identify you.

If you withdraw consent, no new data will be added to the database, but data already collected will still be used.

Coded data may be shared with third parties or other countries, but it will never include direct identifiers (e.g., name, initials, address, national ID, social security number). If

shared, it will only be for the purposes of this study or for scientific publication, always under applicable confidentiality laws.

Withdrawal of Consent

You may withdraw your consent to participate in the study at any time by indicating this on the consent form. If you do so, no further data will be collected, and you may request destruction of any previously obtained identifiable samples.

Study Exclusion

You may be withdrawn from the study at the investigator's discretion for safety reasons, adverse events, or failure to follow the study protocol. If this occurs, you will be informed of the reason.

Other Information

A description of this clinical trial is available upon request at the investigator's office.

What happens when the study ends?

After the study, you will continue with standard postoperative follow-up and radiographic monitoring of your knee prosthesis.

Contact Information

If you have any questions or need more information during your participation, please contact:

Dr. Inmaculada Neira
Orthopedic Surgery Department, Hospital Universitario Santa Cristina
Phone: +34 91 557 43 00, Ext. 320

Version 3.0
March 20th, 2022

PARTICIPANT CONSENT FORM

Study Title: Knee Arthroplasty Surgery: Short-Term Effect of Robotic Assistance (ROSA)

Principal Investigator: Dr. Inmaculada Neira Borrajo

Site: Hospital Universitario Santa Cristina

I, _____

☐ Have read the information sheet provided to me.

☐ Have had the opportunity to ask questions.

☐ Have received sufficient information about the study.

☐ Have spoken with Dr. Inmaculada Neira Borrajo.

☐ Understand that my participation is voluntary.

Withdrawal:

I understand that I may withdraw from the study:

- At any time
- Without giving any reason
- Without affecting my medical care

I will receive a signed and dated copy of this consent form.

I freely give my consent to participate in this study.

Patient Signature _____

Date ____ / ____ / _____

Investigator Signature _____

Date ____ / ____ / _____

Legal Representative (if applicable)

Signature _____

Date ____ / ____ / _____