Informed Consent to Participate in a Research Study

Study title: A Randomized Controlled Trial Comparing Efficacy, Ergonomics, and Safety of ILY Robotic System vs Manual Flexible Ureteroscopy in Patients Undergoing Laser Lithotripsy for Kidney Stones
Principal investigator's name: Dr. Albert El Hajj
IRB ID number: BIO-2024-0452
Document type: Adult consent
Document sub-type: Not applicable
Study site(s): AUBMC and other centers (TBA)
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You are being invited to participate in a clinical research study conducted at the American University of Beirut (AUB). The study has received approval from the Institutional Review Board (IRB) at AUB. You will receive a signed copy of the complete informed consent form.

Please take the time to thoroughly read the information provided below before deciding to participate in this study. If you require additional information or clarification regarding the contents of this form or the study itself, feel free to ask the investigator whose name is stated above or the research team member who provided you with this form. Your participation is entirely voluntary. Refusal to participate will involve no loss of benefits and you have the right to withdraw from the study at any point after signing this consent without affecting your benefits or relationship with your treating physician or AUB/AUBMC.

WHAT IS THE PURPOSE OF THE STUDY?

Innovations in the treatment of kidney stones include lithotripsy using **manual flexible ureteroscopy** or **robotic technology,** both of which are considered the standard of care for minimally invasive stone management**. ILY® robotic system** is a new wireless-controlled manipulator manufactured in France. The tests conducted to evaluate the safety and efficacy of the robot yielded positive results.

Definitions to Consider:

- Lithotripsy is a medical procedure that uses special equipment to break kidney stones or other stones in the urinary system into smaller pieces.
- A digital flexible ureteroscope is a thin, bendable tool with a tiny camera and light at the end, designed to go into the urinary system to see inside the kidney and ureters (the tubes connecting the kidney to the

bladder) in real time.

The aim of our study is to determine whether the **ILY robotic system** is as effective as the **manual method** and collect data about patient safety and other intra-operative parameters like surgeon safety and radiation exposure.

HOW WILL PARTICIPANTS BE IDENTIFIED AND RECRUITED?

This is a multicenter study conducted at several hospitals and medical centers. The subjects to be recruited from all centers are 152 and from AUBMC specifically there are 60 patients.

Eligible participants will be identified from patients who are scheduled for kidney stone treatment, by the Principal Investigator (who is also the treating physician). Participants will be identified and approached by their treating physician during their clinic visit or inpatient if they are admitted from the Emergency Department based on predefined inclusion criteria.

If you are eligible:

1- A member of the research team will approach you in a private setting to explain the study.

2- You will have the opportunity to ask questions and decide whether to participate.

3- If you agree to participate, you will be asked to sign this consent form or, when appropriate, a legal representative can sign the form instead.

Your participation involves no additional cost, and your medical care will not be affected by your decision to participate or not.

Disclaimer:

You cannot participate in this study if you are pregnant. If you can become pregnant, a pregnancy test will be performed before you are exposed to any radiation. You must tell us if you may have become pregnant within the previous 10 days because the test is unreliable during that time.

WHAT HAPPENS IF I AGREE TO PARTICIPATE IN THIS RESEARCH STUDY?

If you agree to participate:

- You will be randomly assigned to one of two groups:
  - Treatment Group (group 1): Undergoing kidney stone treatment with the ILY robotic system.
  - Control Group (group 2): Undergoing kidney stone treatment with the manual flexible ureteroscopy method.

- Both procedures are performed under general anesthesia and are standard methods for treating kidney stones. Both procedures have similar durations. The expected duration of the procedure, whether performed manually or robotically, is approximately 20 to 45 minutes but may be longer depending on individual case characteristics.

- Before the procedure, we will collect information about your demographics and medical and surgical history directly from you and from medical records, and you will undergo a non-contrast CT (NCCT) scan, which is part of standard care.

- After the procedure, we will monitor any complications or side effects and document your length of hospital stay. One month (30 days) after the procedure, you will be asked to undergo another NCCT scan to check for stone clearance, and we will also assess for any complications that may have occurred following the procedure.

- You will remain enrolled in the study until the follow-up CT scan is completed one month after your surgery.

- The process of randomization is done by chance, similar to flipping a coin or drawing a name from a hat, to ensure fairness and eliminate bias. Neither the Principal Investigator (PI) nor the study team has any control over or ability to change the group assignments. This method is used to ensure that the study results are scientifically valid and reliable.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The usual risks of standard procedures for treating kidney stones include:

- Postoperative pain: Temporary discomfort following the procedure.
- Infection: Typically treated with antibiotics.
- Bleeding (hematuria): Blood in the urine.
- Ureteral injury: A rare complication that may require additional intervention.
- Stone migration: Movement of stone fragments during treatment, which may necessitate further procedures.

Potential risks associated with participation in this study:

1. General Anesthesia

Both procedures used in this study require the same type of general anesthesia.

2. Risks of Manual Flexible Ureteroscopy (Standard Surgery)

The known but rare risks are:

- **Injury to the ureter** (the tube that connects the kidney to the bladder)
- **Infection or sepsis**
- **Blood in the urine** (hematuria), which usually goes away on its own.

3. Risks of Robot-Assisted Lithotripsy (ILY Robotic System)

The risks specific to the robotic system include:

- **Technical malfunction** of the robot (rare). If this happens, the surgeon would switch to the standard manual method to finish the surgery, which has no impact on the patient.

So far, **there is no evidence that the ILY® robotic system increases the risk of complications compared to the standard manual method. Early studies have shown that both methods are similarly safe.**

In case of any complications, you will receive immediate medical attention following standard care practices.

Protection against potential risks

To minimize risks, the following measures will be taken:

1- All procedures will be performed by experienced surgeons following established safety protocols.
2- Any adverse events will be promptly managed according to standard medical practices.
3- Your health will be closely monitored during and after the procedure to identify and address any complications early.

All equipment used will be routinely checked by the medical engineering department as per standard protocols. Additionally, and before each procedure the OR nursing team will check the equipment as per standard practice.

Complications that can occur will be dealt with accordingly:

- Ureteral injury: A DJ stent will be inserted
- Infection or sepsis: Treated as per the center's own antibiogram/protocol
- Hematuria: increased hydration and monitoring

Definition: A **DJ stent** (also called a **double-J stent**) is a thin, flexible tube that is placed inside the **ureter** (the tube connecting the kidney to the bladder). It helps **keep the ureter open** so that urine can flow from the kidney to the bladder properly.

While every effort will be made to ensure your safety, there may be risks associated with the procedures that are currently unknown or unforeseeable.

Also, although there are no proven harmful effects from radiation levels the patients will be exposed to during this study, long term effects on his/her health cannot be ruled out with certainty.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

There are no direct benefits to you from participating in this study. However, the information gained from this research may help us better understand the effectiveness, safety, and advantages of the ILY® robotic system compared to manual techniques. This knowledge has the potential to improve kidney stone treatment procedures in the future, benefiting patients and advancing surgical care.

IF YOU DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE ALTERNATIVES?

Your participation is voluntary.
If you choose not to participate in this study, you will still receive the usual standard of care treatment for kidney stones. The standard treatment in your case is manual flexible ureteroscopy (fURS) with laser lithotripsy, performed without the use of a robotic system.
Your decision will not affect your medical care, and you will continue to receive the appropriate treatment for your kidney stone.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

If you agree to participate in this research study, your information will be kept confidential. Unless required by law, only the principal investigator, the co-investigators, and the Ethics Committee will have direct access to your medical records.

Consent forms and clinical data will be stored in a locked cabinet, accessible only by the principal investigator (PI) and the research team.

Participants' data will be coded and stored in a secure file on a password-protected computer with access restricted to the PI and research team.
Results from the study may be published, but no identifying information will be included.

If you decide to withdraw from the study at any point, the data collected till the point of withdrawal remains part of the study database and may not be removed.

WHAT ARE THE COSTS TO YOU?
There will be **no additional costs** for you due to your participation in this study. The study does not cover the cost of the procedure itself, as it is already part of your planned treatment.

WHAT ABOUT COMPENSATION?

There will be **no financial compensation** for participation in this study. However, you will not incur any additional costs related to the study.

WHAT ABOUT RESEARCH-RELATED INJURIES?
Research-related injuries are not expected in this study, as the procedures involved are considered minimal risk. Both techniques being compared—the ILY® robotic system and manual flexible ureteroscopy—are standard, well-established methods for treating kidney stones. Previous clinical assessments have demonstrated their safety profiles.
In the unlikely event of any injury directly related to your participation in this study, appropriate medical care will be provided following standard clinical practices. Please note that there is no provision for additional financial compensation for research-related injuries.
AUBMC will cover the cost of treating, on its premises, medical adverse events resulting directly from the medication and/or medical procedures of this research study. Otherwise, it will not cover the costs of medical care for any medical condition or issue.

WHAT ABOUT MY RIGHT TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

Your decision not to participate or to withdraw from the study will not involve any loss of benefits to which you are entitled and will not affect either your relationship with AUB or your access to healthcare at AUBMC.
If any important new information becomes available during the study that might affect your decision to continue participating, we will inform you promptly.

AGREEMENTS:

For future contact:

☐ I consent to being contacted for future research studies. OR

☐ I do not consent to being contacted for future research studies.

INVESTIGATOR'S STATEMENT

I have reviewed, in detail, the informed consent document for this research study with _____ (name of the participant). I have explained the study's purpose, risks, and benefits, and I have answered all the participants' questions clearly. I commit to informing the participant of any research changes or decisions impacting their participation.

Name of investigator or designee: **Signature:**

Date: Time

SUBJECT PARTICIPATION

I have read and understood all aspects of the research study and my questions have been addressed. I voluntarily agree to participate in this research study. If I require further clarification, I can contact (Dr. Albert El Hajj) at _____01) 350 000, ext. 5246 or 5800 or any designated research personnel. If I felt that my questions have not been answered, I will contact the AUB Institutional Review Board for human rights at (01) 350 000, ext.: 5445. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care. I know that I will receive a copy of this signed informed consent.

Name of participant **Signature:**

Date: Time:

Name of legally authorized representative (if applicable): **Signature:**

Date: Time:

Name of witness (if applicable): **Signature:**

Date: Time: