PARTICIPANT INFORMATION SHEET

CLINICAL TRIAL

A Feasibility Trial of a Novel Robotic System for Retrograde Intrarenal Surgery

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Invitation

You are invited to participate in a research project using a novel surgical robot for retrograde intrarenal surgery (RIRS). The objective of this study is to evaluate the applicability of the robotic system and the effectiveness of the tele-operation control and supervised autonomy in this surgical procedure.

In conventional RIRS, a surgeon manually controls a flexible ureteroscope with surgical instruments, e.g., laser fiber and stone basket, for stone treatment. The robotic system allows the surgeon to control the procedure ergonomically via tele-operation control to improve the precision and stability. Besides, supervised autonomy enables the robot to help control the ureteroscope and laser fiber in the most suitable suitable position for operation. Other workflows, such as stone fragmentation and dusting, remain the same as in the standard RIRS procedure.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The purpose is to investigate the suitability and effectiveness of a novel surgical robot for RIRS.

2. 'Why have I been invited to participate in this study?'

You are invited to participate in this study because your health conditions are in line with the inclusion criteria of this study.

3. 'What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is entirely voluntary. It is completely up to you to decide whether you would like to participate. The treatment that you would receive and your relationship with the staff taking care of you would not be affected if you decide not to participate.

New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may affect your willingness to participate in the study.

If you wish to withdraw from the study after giving the consent, you may do so before the surgery

without giving any reason.

4. 'What does this study involve?'

In this study, a robot will be used to hold and manipulate the flexible ureteroscope and instrument, and the surgeon can control them remotely to the optimal position during the surgery. Compared to manual control, the tele-operation control and supervised autonomy can improve the precision and efficiency.

The stone fragmentation and dusting procedure of this study is still controlled by the surgeon as same with the standard procedure. The set-up time for the use of the robot would not exceed 10 minutes and would not prolong the OT time significantly. If the robot works well as we anticipate, the OT time might even be shorter. Use of flexible ureteroscope and instrument is a standard practice for RIRS and its usage does not pose any significant risk. We have limited experience of using the robot in human as well as cadaver and the robot works well. With many built-in safety features of the robot, the risk of injury by the robot is extremely unlikely. If the robot cannot provide effective assistance during the study, it would be removed and the surgery would be completed in the usual manner.

If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

5. 'How is this study being paid for?'

The study is not sponsored by any commercial company. Individual researchers would not have any financial gain besides the salaries that are paid to them by the university or the hospital.

6. 'Are there risks to me in taking part in this study?'

All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. The risk profile of robotic assisted RIRS is identical to that of conventional RIRS, and has been documented in the consent form for the surgery. Moreover, any anticipated risks have been reduced to a minimum by various measures (e.g. the surgeons are trained, engineers and developers of the robot will monitor the performance of the robot throughout the surgery, and the robot is built with many safety mechanisms). There were no inadvertent injuries in the pre-clinical studies.

7. 'What happens if adverse event occur as a result of the study?'

The anticipated risks of this intervention are not expected to exceed those associated with the standard of care. The participants will be continually monitored if they suffer from any adverse event, till resolution of the event. All patients who experience an adverse event (AE) will be evaluated at appropriate time intervals until the event resolves or stabilizes. At the conclusion of the study, the investigator will assess unresolved AE and determine if additional follow-up is warranted based on clinical assessment

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8. 'Will I benefit from the study?'

Performance of human surgeon may deteriorate due to physical fatigue. The robot instead gives a

more stable and precise positioning throughout the procedure. The tele-operation control and supervised autonomy approaches allow the surgeon to control the robot remotely to optimize the ureteroscope position to facilitate the surgical procedure. This may improve the safety and work efficiency.

9. 'Will taking part in this study cost me anything, and will I be paid?'

Participation in this study will not cost you anything and you will not be paid.

10. 'How will my confidentiality be protected?'

Any identifiable personal clinical information and research data collected in connection with this study will remain confidential. The relative data will be kept for 5 years and used for research purposes only. Only project staff will have access to data. All the data collected would be anonymized. Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer within or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. After the storage period, all data will be completely destroyed without any personal information identifiable. Result of the study will be published in an international journal without revealing your identity.

This study has been approved by The Joint Chinese University of Hong Kong – New Territories East Cluster Clinical Research Ethics Committee (The Joint CUHK-NTEC CREC), therefore The Joint CUHK-NTEC CREC may review the information in the study for ethics review purpose. If you have any enquiry on the rights as a participant, you can contact: The Joint CUHK-NTEC CREC 3505-3935.

11. 'What happens with the results?'

The final results of this research may be presented at conferences, professional journals and thesis. In any publication, information will be provided in such a way that no participant can be identified. Results of the study will be provided to you upon request.

12. 'What happens to my treatment when the study is finished?'

There will not be any change in the treatment and follow up.

13. 'What should I do if I want to discuss this study further before I decide?'

The doctor in charge of this study is Professor NG Chi Fai and Dr Alex Qinyang Liu, who can be reached at 3505-3933. All questions or concerns regarding this study will be answered by Dr Liu.

Thank you for taking the time to consider this study.

If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

Participant Consent Form

I _____ declare that I agree to participate in the clinical trial of the "A Pilot Study of a Novel AI-Powered Robotic System for Autonomous Retrograde Intrarenal Surgery" The objective of this research is to evaluate the applicability of the robotic system and the effectiveness of the tele-operation control and supervised autonomy methods. I understand that the participation is completely voluntary.

I understand that the procedures are, in general, the same as those in the conventional RIRS. The only difference is that the flexible ureteroscope and instrument are held by a robot developed by the research team and the surgeon can control the movement of the robot.

The participation in this clinical trial is completely voluntary and the participants can terminate the participation anytime without any affect to the treatment and care in the hospital. The data collected will be kept confidentially without identification of the subject. The relative data will be kept for two years and used for research purposes only. Only project staff will have access to data. The final results of this research may be presented at conferences, professional journals and thesis.

I understand that sections of any of my medical notes may be looked at by responsible individuals from The Chinese University of Hong Kong and the institutional review board/ ethics committee. Here, I authorize the CUHK-NTEC Clinical Research Ethics Committee as one of the parties to access my records related to the study for ethical review in this study.

The participation has been explained the details of the trial in the interview. Should there be any questions, please contact the Dr Alex Liu at 3505 3933

Name of Participant _____ Signature _____

Date _____

Consent Form explained by _____ Signature _____

Date _____