A Multicenter Randomized Controlled Trial Assessing the Efficacy of Antimicrobial Prophylaxis for Extracorporeal Shock Wave Lithotripsy on Reducing Urinary Tract Infection (APPEAL Trial)

LETTER OF INFORMATION

INVESTIGATOR(S)

Dr._____, Dr. _____ & Dr. _____

INTRODUCTION

You have been invited to participate in a research study to evaluate the use of an antibiotic to prevent urinary tract infections in patients who undergo extracorporeal shock wave lithotripsy (SWL) and often referred to as "Lithotripsy". Up to 1500 patients at participating centers will be enrolled in this study.

PARTICIPATION

If you agree to participate, prior to your SWL procedure, you will be asked to complete a questionnaire about your urinary symptoms that will take about 5 minutes to complete. Information from your medical record will be collected and you will be asked questions about your medical history to assess your eligibility to participate in this study.

If you are eligible for the study, you will be randomly (like the flip of a coin) selected to receive one intravenous (into a vein) dose of an antibiotic called ciprofloxacin or a placebo, which is the same as the study drug but without the active ingredient. Ciprofloxacin is a standard antibiotic used routinely in patients to treat urinary tract infections. You will have an equal chance, (1:1 or 50/50 chance) of being selected to receive the antibiotic or the placebo that will be given to you prior to your lithotripsy procedure. You will not be told which group you are randomized to, but if needed, the pharmacist can provide that information. Information about your SWL procedure will be gathered from your medical record and included in the study's data analysis.

On Day 7 following your SWL procedure, you will go to a laboratory that is convenient to you and provide them with a fresh voided urine sample to determine whether of not you have a urinary tract/bladder infection. It is important that you use the requisition we give you so that the results will be reported to the urologist who performed the Lithotripsy procedure, the study doctor and to your referring urologist. Should your urine culture result indicate/show that you have an infection, the study doctor will contact your local pharmacy and prescribe an antibiotic for you.

You will be given 2 follow-up questionnaires that ask about any difficulties that you have experienced and how your urinary symptoms have been. These are to be completed and returned to us on Day 7 following your SWL procedure. The questionnaires will take you approximately 10 minutes to complete.

RISKS

Side effects specific to the study antibiotic (ciprofloxacin) are rare but may include nausea, headache, insomnia, constipation, dizziness, abdominal pain, and tendon rupture and allergic reaction (itching, skin rash, fever, difficulty breathing).

If you are already participating in another study at this time, please inform the study coordinator or the study doctor to determine if it is appropriate for you to participate in this study.

BENEFITS
It is possible that treatment with an antibiotic prior to shock wave lithotripsy decreases the risk of developing a urinary tract infection and associated urinary symptoms. Your participation in this research may help future patients.

ALTERNATIVE TREATMENTS
The alternate to not participating is to undergo SWL and not be randomized to receive a dose of the antibiotic, Ciprofloxacin or placebo, as part of the study.

CONFIDENTIALITY
By agreeing to participate in this research trial, you consent to allow the investigator (study doctor) and other authorized personnel to use your personal health information for the purposes of conducting the trial. This information will not be used for any other purpose. Your information cannot be released to any other party without your permission. This information will be kept in a secure location. The file which contains your personally identifiable information will be kept separate from the study data. Any publication of results will use only pooled information and you will not be personally identified.

Representatives of _____ Research Ethics Board may follow-up with you to monitor the conduct of the study.

VOLUNTARY PARTICIPATION/WITHDRAWAL
Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study at any time with no effect on your future care. To protect the integrity of the study, you will not be able to withdraw your data from the study after your data has been sent for analysis. You may also be withdrawn from this study without your permission, if, in the opinion of the investigator/your treating urologist, further participation would not be in your best interest.

You do not waive any legal right by signing the consent form. Every precaution will be taken to prevent any complication to you during the study. However, if a complication does occur, you will obtain medical care in the same way that you normally would obtain your medical care.

STUDY COSTS/COMPENSATION
You will not be paid for your time, or reimbursed for any travel expenses for taking part in this study.

CONTACTS/MORE INFORMATION
Please keep this Letter of Information and if you have any questions, at any time during this study, contact your study doctor who can be reached at _____.

Or, you may contact _____, the study nurse working with the study doctor(s)/urologist(s) at _____.

In case of emergency, please go to your nearest hospital emergency department.

If you have any questions concerning your rights as a research participant or the conduct of the study you may contact _____ at _____.

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CONSENT FORM

I, _____ have read the Letter of Information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

_____ _____

Date Signature of Participant

_____

Name of person responsible for obtaining this consent

_____ _____

Date Signature of person responsible for obtaining this consent