Janus kinase-STAT Inhibition to Reduce APOL1 Associated Kidney Disease (JUSTICE)

NCT05237388

IRB Document Date: 30 September 2025

Duke University Health System

Consent to Participate in a Research Study
ADULT

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The purpose of this study is to determine if the drug, baricitinib, is safe and effective in reducing high levels of albumin in the urine (albuminuria) in African American/Blacks with APOL1-associated focal segmental glomerulosclerosis (FSGS) and APOL1-associated chronic kidney disease due to hypertension (HTN-CKD).

Your study participation will last for six months and will include 8 study visits: one baseline screening visit to determine eligibility, six monthly study visits, and one end of study visit. At each of these visits, we will review your medical history and medications and conduct a brief physical exam to assess and monitor your blood pressure, heart rate and weight. We will also collect urine and blood samples for labs used to determine eligibility at the screening visit and then to assess and monitor your health throughout the study.

Once your eligibility is confirmed, you will be randomly assigned (like the flip of a coin) to receive either a placebo or baricitinib, which you will take daily, along with your regular medications, for 4 months.

There are risks to this study drug that are described in this document. The major risks are infections including herpes zoster (shingles), tuberculosis, fungal infections, and other infections; skin cancers and cancers of the lymphatic system; blood clots in the deep veins of the legs, in the lungs, and in the arteries; major cardiovascular events, and lab abnormalities on blood tests.

You are being asked to take part in this research study because you carry a specific gene and have kidney disease. Specifically, you have APOL1-associated FSGS or APOL1-associated chronic kidney disease (CKD) due to hypertension (high blood pressure) (HTN-CKD). Being a part of a research study is a choice. Research studies include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The purpose and design of the study, risks, discomforts, inconveniences and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Dr. Opeyemi Olabisi is the Principal Investigator (PI) for this study, which is sponsored by a grant from the National Institutes of Health (NIH). Portions of Dr. Olabisi's salary will be paid by this grant.

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WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Dr. Opeyemi Olabisi will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate how safe and effective the drug, baricitinib, is in reducing albuminuria (high levels of albumin in the urine) in African American/Blacks with APOL1-associated FSGS and APOL1-associated CKD due to hypertension (HTN-CKD.) Baricitinib is still being tested in research studies and has not yet been approved by the Federal Drug Administration (FDA) for use in kidney disease and is considered an investigational drug. However, this drug has been FDA approved for other diseases, such as rheumatoid arthritis.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 75 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Screening Visit:

If you agree to be in this study, you will be asked to sign and date this consent form and complete a screening visit. You may choose to complete study visits, including urine and blood sample collection, either at home or at the clinic. Weekend visit options may also be available, depending on staff availability. At this visit, the following tests and procedures will be conducted to confirm that you are eligible to participate:

- Review of medical history and medications
- Brief Physical Exam
- Vital signs and weight
- Blood tests
- Urine collection

Enrollment and Randomization:

If you are determined to be eligible, you will be enrolled and given a study ID number. You will then be randomly assigned (like flipping a coin) to receive either a placebo or baricitinib. You will have a 2:1 (67%) chance of receiving baricitinib. A placebo is an inactive substance (no medicine in it) given in the same form (for this study a pill) as the active study drug, baricitinib."

The randomization is double-blinded, which means neither you nor the study team will know if you are receiving the placebo or baricitinib. The research study pharmacist will be the only one “not blinded” and will dispense a month’s supply of your assigned study drug at each of your 6 monthly visits. You will take one pill daily along with your regular medications.

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Monthly Study Visits:
You will be asked to bring your study drug with you to each of the monthly study visits so that the study staff can count the number of pills of you have left. Staff will also ask if you have changed any of your medications and how you have been feeling since the last time they saw you. At each monthly visit the following procedures and tests will be conducted:

- Brief physical Exam
- Vital Signs
- Blood tests
- Urine collections
- Review of study drug compliance (count pills not taken)
- Receive study medication for next month

Cell lines
Another goal of this research is to discover predictors of positive response to baricitinib. Towards this end, this research will also create induced pluripotent stem cells (iPSCs) from blood collected from study participants. The iPSCs will be studied and shared with other researchers that are working on this study. The knowledge gained from the study of the iPSCs will be shared with researchers and healthcare providers that may help other patients with APOL 1 – mediated kidney disease. It will not be possible to identify you via these cells. Our hope is that this knowledge would help doctors determine ahead of time which patient with kidney disease is most likely to benefit from baricitinib.

- **iPSC: Induced Pluripotent Stem Cells:** What are iPSC's? "Pluripotent" stem cells are cells that can be converted into many different kinds of cell types, such as muscle, nerve, and kidney cells. They can be kept alive and stored indefinitely in the laboratory and cell banks. There are different kinds of pluripotent stem cells. Induced pluripotent stem cells (iPSCs) can come from many different types of donor samples, such as skin, blood, or hair. This is different from embryonic stem cells, which can only come from embryos. This study involves the creation and use of iPSCs that come from donated blood samples.

  We can learn a lot by studying iPSCs that are made from samples collected from people with different conditions, and people without these conditions. iPSCs are used for research on various medical conditions and potential treatments for those conditions. They are also used to develop better techniques for making iPSCs and to train researchers in how to make them.

_____ Yes, I consent to providing a blood sample for iPSC samples to be generated at Duke Molecular
Initials Physiology Institute for continued research of the JUSTICE study.

_____ No, I do not want to provide a blood sample for iPSC samples for continued research of the
Initials JUSTICE study.

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The Duke Research Equity and Diversity Initiative (READI) aims to better understand and improve participants' experiences in research studies. If you agree to share your contact information (name and email address), you may be invited to share additional information on your experience (e.g., through surveys). Sharing your contact information is completely optional and does not impact your participation in this study. Please indicate if you are willing to share your contact information:

____ Yes, I am willing to share my contact information with the READI project.

____ No, I do not want my contact information shared.

End of Study Visit:
After you complete the 6 monthly study visits and your final dose of the study drug you will be asked to complete the End of study Visit, which will include all of the same tests and procedures conducted during the monthly visits, except you will not receive any more study drug.

Early Withdrawal Visit:
If for some reason you stop taking the study medication or withdraw from the study before you have completed the 6 months of study intervention, you will be asked to complete a final visit in order for us to conduct the same tests and procedures that would have been done at the end of the study.

HOW LONG WILL I BE IN THIS STUDY?
If after your baseline screening visit you are determined to be eligible, you will be in the study for six months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
The risks of participating in this study are associated with study procedures (blood draws), the potential for breach of patient confidentiality and the possible side effects associated with taking baricinitib, and if participant choses to receive, risks associated Herpes vaccine for Shingles. Every effort will be made to minimize each of these potential risks during your study participation.

Blood Draws:
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Shingles vaccine: Receiving the Shingles vaccine is voluntary and has benefits for the participant. The following are the most common risks associated with this:

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- **Arm pain**
- Redness and swelling at the injection site
- Felling tired
- Muscle pain
- Headache
- Shivering
- Fever
- Stomach pain or nausea

Breach to Patient Confidentiality
Due to the necessity of reviewing data from your Duke medical record, breach to patient confidentiality poses a potential risk. To minimize this risk, all data collected will be entered electronically into the study's secure database, where it will be stored and de-identified (assigning a code) before becoming available for analysis.

Taking Baricinitib:
The risks of taking baricinitib have been extensively studied for more than 8 years in large, randomized multicenter studies involving nearly 4,000 patients with rheumatoid arthritis. One of the safety parameters studied was the incidence rate of the most significant risks factors: serious infections, malignancy (cancer), major cardiovascular events and blood clots in the leg (DVT) or lungs (PE). Serious infection incidences for participants receiving a placebo was compared to participants receiving various doses of baricinitib, and the results of that comparison showed no major differences in infection rates. As a result of your participation in this study, you may be at risk for all, some or none of the side effects associated with taking baricinitib listed below. You may want to discuss this list with the study doctor and your regular health care provider to address any of your concerns or questions. Allergic reactions have been seen with baricitinib. Examples of an allergic reaction include: rash; wheezing; itching, or swelling. If any of these reactions are severe, you should get immediate medical help and contact the study doctor if you have any of these or any other severe side effects during the study.

<u>Potential Side Effects of Taking baricinitib:</u>

- Infections some of which may be serious because study drug suppresses the immune system.
  - Herpes Zoster (shingles)
  - Tuberculosis (if you have had a prior exposure)
  - Opportunistic infections including invasive fungal infections
- Arterial blood clots including heart attacks and strokes
- Deep Vein Thrombosis (DVT) (blood clots in the deep veins of the legs)
- Pulmonary Embolism (PE) (blood clots in the lungs)
- Cancers
  - Non-melanoma skin cancer
  - Lymphoma (cancer of the lymphatic system)

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- Lab abnormalities
  - Anemia (Hgb <8g/dL), which means that the red blood cell count is low
  - Neutropenia (ANC<1000 cells/mm3), which means that a type of white blood cell count is low
  - Lymphopenia (ALC<500 cells/mm3) which means that another type of white blood cell count is low
  - Elevated LDL and HDL, which means an increase in cholesterol in the blood
  - Elevated ALT/AST, which means liver functioning results are outside of normal levels

- Death

Potential Risks and the Genetic Information Non-Discrimination Act (GINA): There is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed. The genetic information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location at DUHS, accessible only by authorized members of the study team, and will not be disclosed to third parties except as described in this consent form, with your permission, or as may be required by law.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Incidental Findings: It is possible that this study will identify information about you that was previously unknown, such as disease status or risk. There are no plans to provide this information to you or your physician unless the information indicates that you may be at risk for a serious illness known at the time of testing to be treatable. In that case, we will attempt to notify you using the contact information you have provided, so that you can speak with Dr. Opeyemi Olabisi at Duke University Health System (DUHS**).** DUHS staff will not provide this information in a voice mail, email, or otherwise prior to contacting you. **Please notify us of any change in your contact information.**

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If you do not want to be notified of any incidental findings, please initial below.
_____ Please do not notify me of any incidental findings obtained from this research.
Initials

If you prefer, we can ask you at the time of notification whether or not you want to receive incidental findings information. In this case, please initial below.

_____ Please ask me at the time of notification whether or not I want to receive incidental findings
Initials information.

If at any time during or after the study you change your mind about whether or not you would like to be notified, you can contact us at (919) 660- 6987.

After providing the information to you, Dr. Olabisi may arrange for you to meet with him/her and/or a genetic counselor or refer you to another appropriate health care provider to review the incidental findings information with you or your physician.

Other Considerations:
Other things to consider when making your decision to participate in this study include:

- Reproductive Risks: Pregnancy in women with APOL1 disease is associated with an increased risk of complications for mothers and babies. In addition, baricinitib may have additional risks. For these reasons, in women who could possibly become pregnant, a blood pregnancy test will be one of the tests done at the screening visit. In women 40 years old and older, blood pregnancy tests can sometimes give a false positive or indeterminate result and additional testing may be required. If you have a partner who is able to father children, you and your partner must agree to use a highly effective method of birth control for the duration of the study and for one month after the last dose of study drug. Because some methods may not be safe to take with the study drug, the study doctor will review methods with you to make sure that the one that you choose is appropriate for your medical condition and the level of effectiveness required by this study. Because no method of birth control is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant. If pregnancy is confirmed, the study drug will be stopped, but the study doctor will continue to follow you to collect information on your health during the pregnancy, and, if appropriate, on the health of the baby.
- Drug and Food Interactions: For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.
- Unknown risks: There may be risks, discomforts, drug interactions or side effects that are not yet known.

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Consent For Receiving Shingles Vaccine:

Baricitinib 4mg is associated with an incidence rate of Herpes vaccine for Shingles versus placebo and higher than the highest study dose being used in this study. Though the risk of Herpes zoster is low there is a risk. As a way to lower this risk the study is offering to those that are interested can volunteer to receive both administrations of the shingles vaccine. Dr. Olabisi will prescribe the vaccine for you and the study will pay for cost associated with the vaccine.

_____Yes: I would like to receive the shingles vaccine.
Initials

_____No: I would not like to receive the shingles vaccine.
Initials

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, you may not benefit from participating in this study. The potential benefit of monthly testing may help you better understand the outlook of your kidney disease and make more informed healthcare decisions. If you receive baricinitib, it may help reduce high levels of albumin in your urine, but there is no guarantee. There are no benefits to taking the placebo. If you chose to accept the Shingles vaccine you will benefit from the improved protection for the virus that causes shingles.

The information learned from this study regarding the treatment of FSGS and HTN-CKD may benefit you and others with these kidney diseases, in the future.

ARE THERE ALTERNATVES TO TAKING PART IN THE STUDY?
If you choose not to participate, you will receive standard (usual) care. Your choice will have no consequences on the quality of care that will be provided to you. Please talk to the study doctor about your options before you decide whether or not you will take part in this study.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, Dr. Olabisi and his study team will collect store information from your medical record as well as information and test results collected solely for the purpose of this research. and store it

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in a secured study database at Duke. Results of tests and procedures done solely for this research study and not as part of your regular care will not be included in your medical record unless it is determined to be clinically significant to your health care. Any research information in your medical record will be kept indefinitely.

All information collected about you for the purpose of this research study will be kept in a research study record, separate from your medical record and may be available to your physicians if needed for your care. However, you will not have access to this research information until the end of the study. Your research record will be kept for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed, or information identifying you will be removed from such study results at DUHS.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1. there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2. you have consented to the disclosure, including for your medical treatment; or
3. the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

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While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private.

If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There will be no costs to you for any of the procedures, tests or medication included in this study. You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Olabisi. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

Eli Lilly will provide the study drug/placebo free of charge to you. At the end of the study, or if you decide to withdraw from the study before it ends, you may be asked to return all unused study drug. You may be asked to return for a checkup before you stop your study drug if Dr. Olabisi thinks that stopping it suddenly may harm you and may ask you to complete the tests that would ordinarily occur when a person completes the study.

WHAT ABOUT COMPENSATION?
If you complete all 8 study visits, you will receive a total of $450 for your participation. Compensation will be made after the completion of each study visit for the following amounts:

- $50: baseline screening visit

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- $50: each of the 7 study visits
- An additional $50 for end of study visit or early withdrawal visit

Payment for participation in research is considered taxable income and Duke University is required in many cases to report this information to the Internal Revenue Service (IRS).

Duke University requires that you provide your name, mailing address, and social security number for this tax reporting purpose before payment can be issued. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

Research subject payments to a non-employee of Duke University adding up to $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Opeyemi Olabisi at 919-660-6987 during regular business hours and at 919-684-8111 after hours and on weekends and holidays and ask that Dr. Olabisi be paged.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
Patients may decide to withdraw from the study at any time. Patients who elect to discontinue the study drug will remain as trial patients and continue to have data collected unless they withdraw from the trial. Data collected prior to withdrawal will remain in the trial database. Contact information for the research personnel will be available throughout the duration of the trial to facilitate communication such as a decision to withdraw from the trial. If you do decide to withdraw, we ask that you contact Dr. Olabisi in writing and let him know that you are withdrawing from the study. His mailing address is Opeyemi Olabisi, M.D., Ph.D. Department of Medicine-Nephrology Duke University Medical Center 2424 Erwin Road, Hock Plaza Suite 605 Durham, NC 27710.

In addition, you must return all unused study drug to Dr. Olabisi or his staff.

Dr. Olabisi may ask you to return for a checkup before you stop your study drug if he thinks that stopping the drug suddenly may harm you. He may also ask you to complete the tests that would ordinarily occur when a person completes the study.

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We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your doctor may decide to take you off this study if your condition gets worse, if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. This may occur if they determine they have all the data needed for the study or if there are any safety or efficacy concerns that arise during the study that need to be reviewed before continuing. If this occurs, you will be notified and your study doctor will discuss other options with you.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Opeyemi Olabisi at 919-660-6987 during regular business hours and at 919-684-8111 (the Duke paging operator) after hours and on weekends and holidays. For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time