Are we achieving patient treatment goals with guideline-based therapy for Psoriatic Arthritis?

NCT03620188

5/12/2020

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Are we achieving patient treatment goals with guideline-based therapy for Psoriatic Arthritis? (PaGoPsA)**

Application No.: **IRB00184580**

Sponsor: **Amgen Inc**

Principal Investigator: **Ana-Maria Orbai, MD MHS**
5501 Hopkins Bayview Circle, Suite 1B1
Baltimore, MD 21224
Phone number: 410-550-9674
Fax: 410-550-2625

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

2. Why is this research being done?

This research is being done to determine if guideline-based Psoriatic Arthritis (PsA) clinical care achieves individual patient goals as reported by patients. This study also is being done to identify the factors of achieving treatment success from the perspective of patients with PsA.

People 18 to 95 years old with PsA seen at least every 6 months in the Johns Hopkins Arthritis Center and the Psoriatic Arthritis Program clinics may join.

How many people will be in this study?
Up to 250 people will be in this study.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

We will ask you complete the following during at most 3 of your clinic visits. Study visits will occur at 3-4 month intervals in conjunction with clinical care. Information collected at today's clinical visit maybe used as one of the 3 visits if you agree to participate in this study.

- Complete a questionnaire on an electronic tablet concerning your overall health, ability to function and take part in life activities and other aspects of living with PsA (such as skin and arthritis symptoms, fatigue, sleep, emotions, etc.).
    - At the very first time we will also collect answers to basic questions about your demographics (age, gender, etc.), your disease (time since diagnosis, symptoms etc.).
    - We estimate it will take about 20-30 minutes to complete the electronic questionnaire.
    - Some of the questions on the tablet may overlap with questions collected in another study that you may be participating in.
- Information about you will be collected from your Johns Hopkins medical record. This information will include things like PsA activity, severity, and length as well as certain laboratory values you may have had done in the past. This clinical information will be compared to other participants in this study.

Future Contact
We would like your permission to contact you about other studies that you may be eligible for in the future.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

NO ☐ _____ _____
Signature of Participant Date

How long will you be in the study?
You will be in this study for about two years. The questionnaire completion will take 20 to 30 minutes at each routine care clinic visit during the year. We expect that you will have up to 3 routine care clinic visits during the study.

4. What are the risks or discomforts of the study?

Questionnaires:
You may get tired or bored when we are asking you questions. You do not have to answer any question you do not want to answer.

Loss of confidentiality:

Although we will do everything we can to protect your privacy, there is the possibility of a loss of confidentiality. You will only be identified by a study number. Only the study director and study coordinator will be able to link your study number directly to you.

Scientists from other countries who are doing similar research might look at the information you provide. Your name will not appear on anything that people outside of Johns Hopkins may look at. We may work with other scientists to analyze the data.

We will always have control over what happens with the results. The results of the study may be reported in professional publications or conferences. You will not be identified in any way in publications or presentations.

5. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. The information you give us in this study will help us better understand how patients experience psoriatic arthritis, treatment, and things that are important to you.

6. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No. A coupon to cover the cost of parking will be provided to you at each study visit.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

10. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

11. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Orbai at 410-550-9674. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach Dr. Orbai or wish to talk to someone else, call the IRB office at 410- 955-3008.

c. What happens to Data that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.

12. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.