The ICONIC-PsA 1 Research Study

This study is evaluating the safety and efficacy of an oral investigational medication for psoriatic arthritis (PsA). Study doctors want to compare the investigational medication to placebo. Placebo looks like the investigational medication but contains no active medication. An active reference medication for PsA will also be used.

While placebo and an active reference medication are used in this study, all participants will receive the investigational medication. These details will be covered later in this booklet.

The investigational medication has not been approved by any regulatory agency for the treatment of PsA. It is only available to people with PsA in research studies like this one. The active reference medication has been approved in some countries and is currently used for patients with PsA.

Participating in this study is not the same as receiving medical treatment. The purpose of this study is to gather information about the investigational medication. However, all participants will be evaluated regularly by study doctors and staff and receive a high level of care and attention.

Doctors and regulatory agencies will use the information gathered in this study to determine if the investigational medication could one day be made available to the public.

To conduct this study, doctors need volunteers like you. By participating in this study, you could help potentially advance research for PsA.

Who can be in this study?

To qualify for this study, you must:

- Be 18 years of age or older
- Have been diagnosed with PsA for at least 3 months prior to beginning this study
- Have at least 3 swollen joints and at least 3 tender joints
- Have active plaque psoriasis or nail changes consistent with psoriasis
- Have never taken a biologic medication for PsA or psoriasis

Additional study criteria will apply. All study-required visits, tests, and medication will be provided at no cost. In addition, reimbursement for study-required travel may be provided.

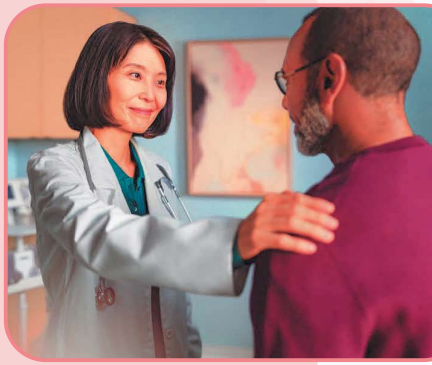
Do I have to join this study?

No, your decision to participate in this study is voluntary. Even if you join this study, you can choose to leave it at any time and for any reason. Leaving this study will not affect any medical care available to you.

However, if you leave the study, you will not be allowed to rejoin the study.

The importance of diversity in this study

The safety and efficacy of the investigational medication may differ by age, sex, race, and ethnicity. As a result, the ICONIC-PsA 1 study wants to include a diverse group of participants. This will help evaluate the safety and efficacy of the investigational medication in the diverse groups of people who may use it.



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What will happen during this study?

There are 5 parts to this study. If you complete all 5 parts, your total study participation will last up to 109 weeks (about 25 months).

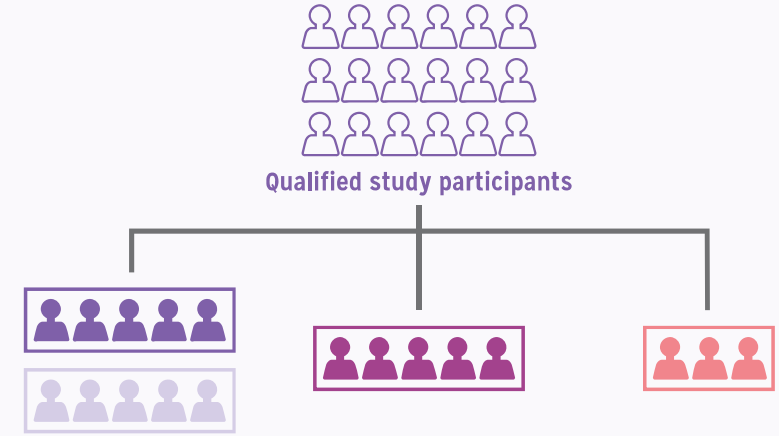
Screening	• Lasts up to **5 weeks** • Includes at least 1 study visit for health exams and tests to determine if you can be in the study • If you are eligible, you will begin the Active-Reference and Placebo-Controlled Study Treatment Period

Active-Reference and Placebo-Controlled Study Treatment Period	• Lasts about **16 weeks**
	• Includes 6 study visits for health exams and tests
	• You will be randomly assigned (by chance) to 1 of 4 study groups:
	  • Groups 1 and 2 will receive one of the oral investigational medication doses
	  • Group 3 will receive oral placebo
	  • Group 4 will receive injections of the active reference medication
	• All participants will take their oral study medication (investigational or placebo) once a day
	• All participants will receive an injection (active reference medication or placebo) at Weeks 0, 4, and 16

Active-Reference Study Treatment Period	• Lasts about **36 weeks** • Includes 6 study visits for health exams and tests • Groups 1 and 2 will continue to receive one of the oral investigational medication doses • Group 3 will begin receiving one of the oral investigational medication doses • Group 4 will continue to receive injections of the active reference medication • All participants will take their oral study medication (investigational or placebo) once a day • All participants will receive an injection (active reference medication or placebo) at Weeks 28 and 40
Long-Term Extension Period	• Lasts about **48 weeks** • This period is optional and may include 4 study visits for health exams and tests • Group 4 will begin receiving one of the oral investigational medication doses • All participants will take the oral investigational medication once a day • No participants will receive placebo or injections
Safety Follow-Up	• Includes 1 study visit **4 weeks** after your last dose of the oral study medication

What are the study groups?

As noted in the previous section, you will be in 1 of 4 study groups:

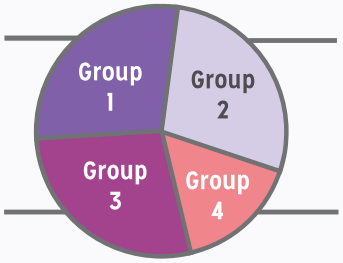


Groups 1 and 2	Group 3	Group 4
• Receives 1 of 2 doses of the oral investigational medication for the entire study • Receives a placebo injection at Weeks 0, 4, 16, 28, and 40	• Receives oral placebo for the first 16 weeks • Receives 1 of 2 doses of the oral investigational medication for the rest of the study • Receives a placebo injection at Weeks 0, 4, 16, 28, and 40	• Receives oral placebo for the first 52 weeks • Receives an injection of the active reference medication at Weeks 0, 4, 16, 28, and 40 • After 52 weeks, receives 1 of 2 doses of the oral investigational medication for the rest of the study

All study groups will receive placebo during this study. Placebo may be given both as an oral study medication and study medication injections.

You have a **28% chance** of receiving the oral investigational medication in Group 1.

You have a **28% chance** of receiving oral placebo (for only 16 weeks), then receiving the oral investigational medication in Group 3.



You have a **28% chance** of receiving the oral investigational medication in Group 2.

You have a **16% chance** of receiving the injectable active reference medication, then receiving the oral investigational medication in Group 4.

You and the study doctor/staff will not know your group assignment or investigational medication dose. In the event of an emergency, this information can be provided.

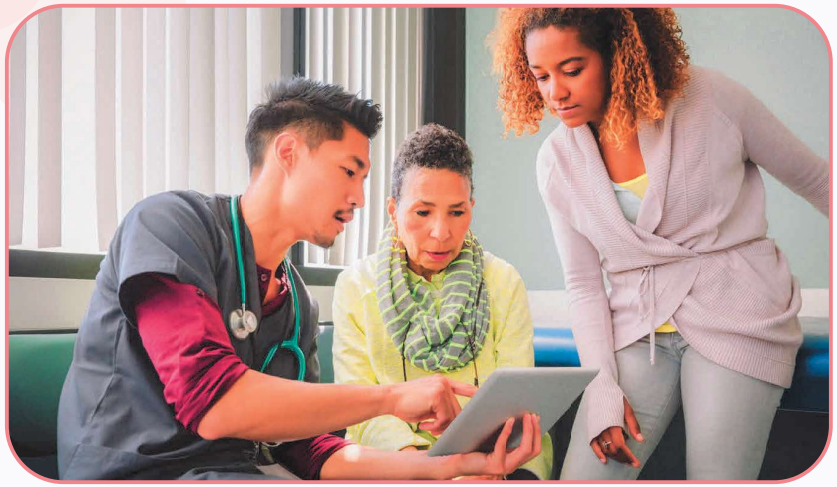
What are the key health exams and tests in this study?

When you visit the study site, the study doctor/staff will conduct various health exams and tests to evaluate your PsA and overall health.

Some of the health exams and tests you could undergo include:

- PsA evaluations
- Psoriasis evaluations
- Questionnaires about your PsA, psoriasis, and overall health/ quality of life
- Physical exams
- Vital signs measurements
- Electrocardiograms (ECG)
- Tuberculosis evaluations
- X-rays
- Blood draws
- Urine samples
- Reviews of your study medication use
- Reviews of medications you are taking
- Reviews of any side effects

Please note that not all health exams and tests will be conducted at every study visit.



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Will my personal health information be protected in this study?

During this study, the study doctor/staff will collect and use your personal health information for research purposes only. This information may include the results of your health exams and tests, as well as your medical history.

Only people who are associated with this study will have access to this information. To protect your identity, a unique code will be assigned to your information. This will remove any identifying information such as your name or date of birth.

As a result, your personal health information will be protected in accordance with all applicable laws and ethical requirements.

Frequently Asked Questions

What are the potential benefits of being in this study?

While you could benefit from study participation, that is not guaranteed. It is possible your condition may improve, stay the same, or get worse.

The study doctor/staff will closely monitor you during the study. Your safety is their primary concern.

If you do participate in this study, you may help others with PsA in the future.

What are the potential study risks?

Before you begin, the study doctor/staff will review a list of all known and possible study side effects with you. This includes potential side effects related to the study medication and health exams and tests.

If new information about the study medication or health exams and tests becomes available, the study doctor/staff will let you know as soon as possible.

What happens if I receive placebo?

While you may receive oral placebo for the first 16 or 52 weeks, you will receive the oral investigational medication for the remainder of the study. If you do receive placebo (oral or injection), it does not contain any active medication. That means it should not affect your condition.

However, some people do experience a placebo effect. When a placebo effect occurs, symptoms may appear to improve.

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Why does this study use placebo?

Using placebo helps the study doctor/staff:

- Better understand the effects (good or bad) of the investigational medication
- Learn if any effects (good or bad) are caused by the investigational medication

Why does this study use an active reference medication?

Using an active reference medication helps the study doctor/staff learn more about how the investigational medication works.

What happens if I want to participate in this study?

After talking with the study doctor/staff, you will meet with them to review the informed consent form (ICF). The ICF is written to help potential study participants better understand what will happen during their participation.

The study doctor/staff will also be able to answer any questions about the ICF. You can also take home a copy of the ICF to discuss with your family, friends, and doctor.

Once you review the ICF and agree to join the study, you will be asked to sign it. This gives your consent to be in the study. You must sign the ICF before any study health exams and tests can begin.

How long are the study visits?

Study visits will last approximately 1 to 2 hours, depending on the health exams and tests that occur.

How often will I take the study medications?

You will take 2 pills (vitamin-sized) with water every day for 100 weeks (or about 2 years). You will receive an injection (active reference medication or placebo) at Weeks 0, 4, 16, 28, and 40.

Will I be able to take other medications during this study?

You may be able to take some medications for PsA. When you meet with the study doctor/staff to review the ICF, they will talk with you about medications not allowed during this study. If a medication is not allowed, you will not be able to take it during the study.