

Clinical Trial Results Summary

A clinical trial to learn about the effectiveness of a questionnaire in detecting psoriatic arthritis early in Korean people with psoriasis

Thank you!

Thank you to the participants who took part in the clinical trial for psoriatic arthritis. Every participant helped the researchers learn more about the effectiveness of a questionnaire for detecting psoriatic arthritis early in Korean people with psoriasis.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CAIN457AKR04

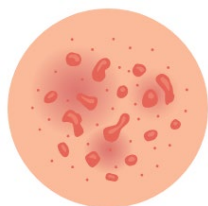
Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial.

What was the main purpose of this trial?

The purpose of this trial was to learn about the effectiveness of a questionnaire, called **Early Arthritis for Psoriatic Patients (EARP)**, in detecting **psoriatic arthritis (PsA)** early in Korean people with **psoriasis**. Researchers compared the results of this questionnaire with the opinion of the trial doctor/skin specialist in detecting psoriatic arthritis during routine medical practice in Korean people with psoriasis.



Skin patches in psoriasis

Psoriasis is an inflammatory skin disease that causes red, bumpy, and scaly patches on the skin.

People with psoriasis may develop **psoriatic arthritis (PsA)**, which causes pain and swelling in the joints and may result in irreversible joint damage.

Continuous monitoring and early detection of arthritis symptoms in psoriasis with prompt treatment may prevent damage to joints.



The **Early Arthritis for Psoriatic Patients (EARP)** is a simple and easy-to-use questionnaire, that can be used in routine medical practice. It is used to identify people who do not have symptoms of PsA yet but might have PsA. It consists of 10 questions related to symptoms of joint disease. Based on the responses, it gives a score between 0 and 10. A score of 3 or more indicates that the person may have PsA and needs further testing to confirm.



The trial's purpose was to answer this main question:

How many participants were correctly identified with psoriatic arthritis (PsA) using the EARP questionnaire as compared to the trial doctor's opinion?

Since participants did not receive any additional treatment in this trial, the trial did not collect any safety-related information.

How long was this trial?



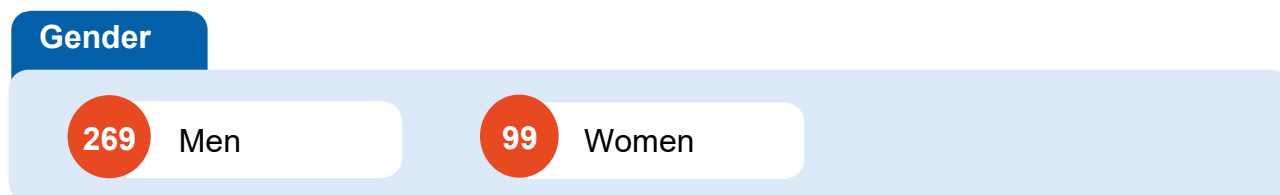
The trial began in October 2022 and ended in June 2023. Each participant was in the trial for one day.

Who was in this trial?



368 participants from Korea entered this trial. Participants' ages ranged from 19 to 79 years. Their average age was 44 years.

All the participants were Asian. The number of participants by gender is shown below.



Participants could take part in this trial if they:

- were 19 years of age or older
- had moderate to severe psoriasis
- had neither been screened for nor diagnosed with PsA previously
- did not have another known skin or joint disease

What treatment did the participants receive?

Participants continued their current psoriasis treatment. They did not receive any additional treatment in this trial.

What happened during this trial?

During the trial

1 day

Participants visited the clinic for one day.

Trial doctors checked the participants' health and looked at their psoriasis history to ensure they could be in this trial.

Researchers randomly divided the participants into 2 groups:



- **EARP questionnaire group:** 181 participants

The PsA risk was assessed based on participants' responses on the EARP questionnaire, according to their symptoms.



- **Trial doctor's opinion group:** 187 participants

The trial doctor assessed the PsA risk as per routine medical practice without using the EARP questionnaire or any other screening tool.

To confirm if they truly had PsA, participants in both groups also had a blood test, to rule out other forms of arthritis, and X-rays on the same day.

No follow-up visit was planned for participants in this trial.

What was the main result of this trial?

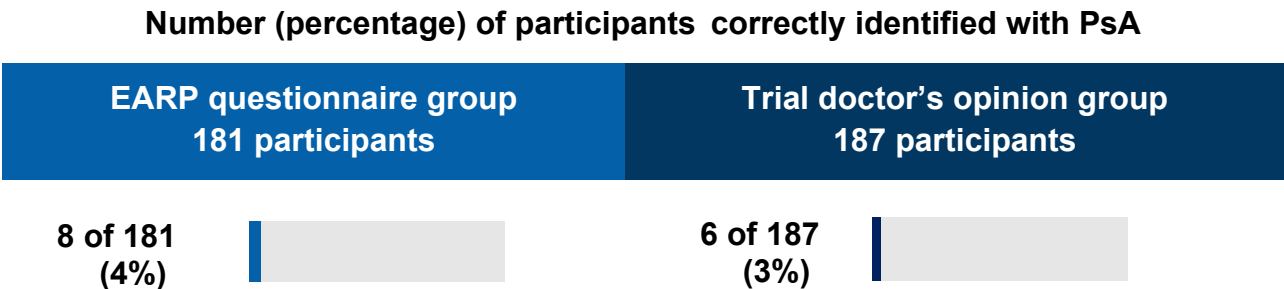
How many participants were correctly identified with psoriatic arthritis (PsA) using the EARP questionnaire as compared to the trial doctor’s opinion?



The number of participants that were correctly identified as having psoriatic arthritis by using the EARP questionnaire or according to the trial doctor’s opinion, was similar.

To answer this question, trial doctors assessed the participants’ symptoms and took blood samples and X-rays to confirm whether the participants had PsA. They used the **Classification Criteria for Psoriatic Arthritis (CASPAR)** for this. This information helped researchers to find the number of participants who were correctly identified as having PsA in each group.

CASPAR is a set of rules used by doctors to diagnose psoriatic arthritis by giving a score. As per CASPAR, having a joint disease with a score of 3 or more confirms psoriatic arthritis.



The CASPAR further confirmed that there were more participants in the **EARP questionnaire group** and in the **trial doctor’s opinion group** who were missed to be identified with PsA.

What were the other results of this trial?

What were the differences between participants who had PsA and those who did not have PsA?



- Out of the total 368 participants, 28 were diagnosed with PsA through CASPAR. This included participants who were correctly diagnosed and those who had PsA but were missed to be identified with PsA in both groups.
- These 28 participants who had PsA had more severe psoriasis symptoms involving the **scalp**, **palms** of the hands, **soles** of the feet, **nails**, and experienced **joint symptoms**, than those participants who did not have PsA.

What was learned from this trial?

Researchers learned about the effectiveness of the **Early Arthritis for Psoriatic Patients (EARP)** questionnaire in detecting psoriatic arthritis early in Korean people with psoriasis.



Researchers found that the number of participants correctly identified as having psoriatic arthritis using the EARP questionnaire was similar to those identified by the trial doctor/skin specialist in routine medical practice in Korea.

Where can I learn more about this trial?

More information about the results of this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website, www.novctrd.com.

Follow these steps to find the scientific summary:



For more information about this trial, go to the following website:

- www.clinicaltrials.gov - search using the number **NCT05758402**

Other clinical trials using AIN457 may appear on the public websites above. When there, search for AIN457 and psoriasis, or psoriatic arthritis.

Full clinical trial title: A randomized, open, parallel, controlled, multi-center, interventional, cross-sectional study to evaluate the detection rate of psoriatic arthritis in Korean moderate-to-severe psoriasis patients, with or without active screening for arthritis in psoriasis (ASAP Study)



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