



Comparing how well abrocitinib and dupilumab treat atopic dermatitis signs and symptoms: a plain language summary

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*At the time this study was conducted

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Summary

What is this summary about?

Atopic dermatitis (AD, also called atopic eczema) is a skin disease that can affect a person for a long time and causes red or flaky skin that can be itchy and uncomfortable. Healthcare providers can prescribe medicated creams and ointments to reduce the visible signs and symptoms of AD, but these treatments are not always enough to keep it under control. A new medicine called abrocitinib is taken every day as a tablet. Abrocitinib works by slowing a part of the body's defense mechanism, called immune response, that is not functioning properly in AD. The clinical study described in this plain language summary, called JADE DARE, investigated how well and how safely 26 weeks of treatment with abrocitinib worked in adults with AD compared to an injected medicine, called dupilumab, that is also approved for AD.

How to say (double-click on the icon to play sound)...

- **Abrocitinib:** ahb-roh-SIT-ih-nib
- **Atopic dermatitis:** ey-TOP-ik dur-muh-TAHY-tis
- **Dupilumab:** doo-PILL-you-mab
- **Eczema:** EG-zuh-muh

What were the results?

The study showed that abrocitinib was more effective than dupilumab in providing itch relief after 2 weeks. In addition, people who were taking abrocitinib for 4 and 16 weeks experienced greater improvement in the visible skin signs of AD than people who were taking dupilumab. The number of people who had health complaints while taking abrocitinib was similar to the number of people who had health complaints while taking dupilumab. Most of these complaints were minor.

What do the results mean?

Abrocitinib was more effective than dupilumab in quickly improving the signs and symptoms of moderate or severe AD in people who did not show improvement with prescribed medications like creams or ointments.

Where can I find the original article on which this summary is based?

You can purchase and read the original article published by *The Lancet* here:
[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)01199-0/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)01199-0/fulltext)

Who should read this summary?

- This article is intended for people who want to learn about medicines for atopic dermatitis (AD, also called atopic eczema).

What is atopic dermatitis?

- Atopic dermatitis (AD), also known as atopic eczema, is a skin disease that can affect a person for a long time
- People with AD have red or flaky skin patches that can be itchy and uncomfortable
- People with AD often say that itching is one of the biggest problems of having eczema
- People with AD usually start their treatment with creams and ointments, which may also contain medicine
- Some people with AD find that creams and ointments, even with medicine, are not enough to control their disease
- People with AD who do not experience enough relief with creams and ointments with medicine can use a stronger kind of therapy, which is injected in the muscle or taken by mouth

What is abrocitinib?

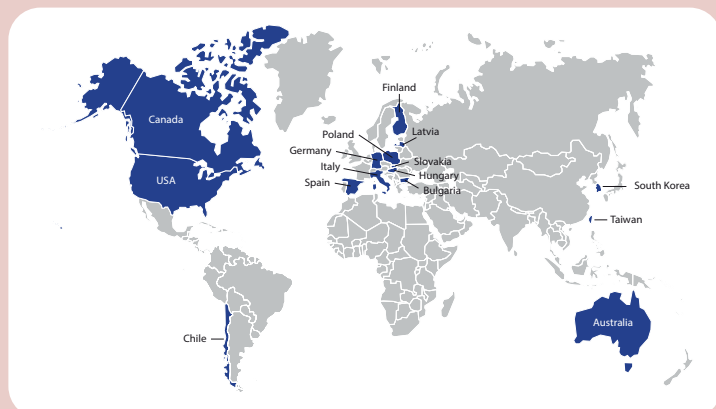
- Abrocitinib is a tablet that is taken by mouth once a day
- Abrocitinib is a medicine that can improve the visible skin signs and itching in patients with AD
- Abrocitinib works by slowing a part of the body's defense mechanism, called the immune response, that is not functioning properly in AD
- Abrocitinib is approved for the treatment of moderate-to-severe AD

What was the JADE DARE study designed to look at?

- The aim of the JADE DARE study was to see how well and how safely 26 weeks of treatment with abrocitinib worked in adults with AD compared to an injected medicine, called dupilumab, that is also approved for AD.

Who took part in the JADE DARE study?

- There were 727 participants from 151 medical centers in 15 countries.



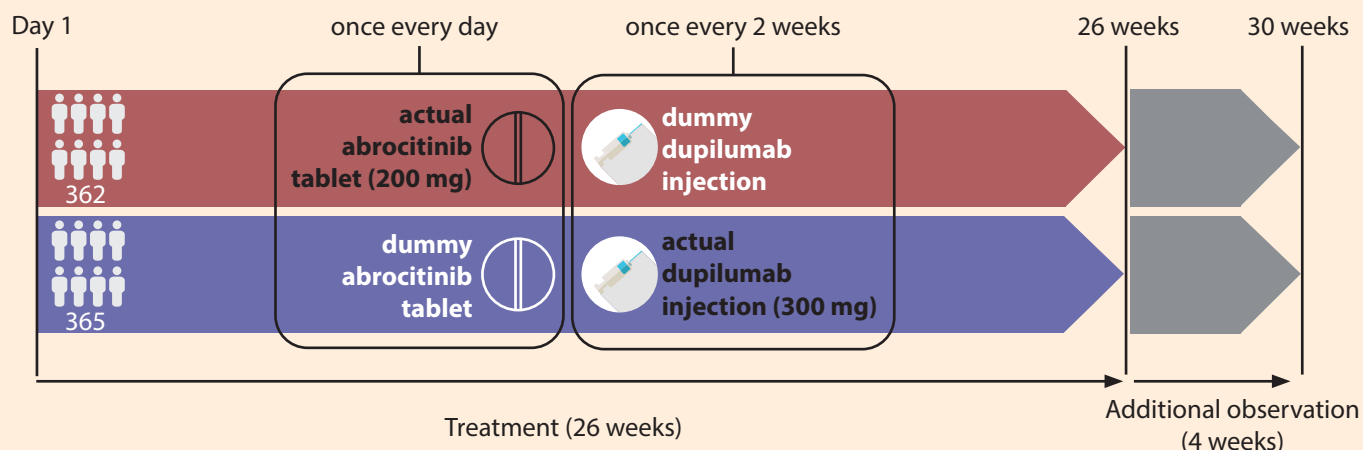
- The study included 397 men and 330 women.
- About 1 in 5 (20%) of participants were Asian, 1 in 14 (7%) were Black or African American, and 7 in 10 (71%) were White
- People who took part in the study:
 - Were adults aged 18 years or over who had been diagnosed by their doctor with AD at least 6 months before beginning the study

- Had been diagnosed by their doctor as having ‘moderate or severe AD’ because 10% or more of their skin was affected by skin patches that were very red and scaly, and because they had at least moderate itching on the first day of the study
- Had AD signs and symptoms that did not improve after at least 1 month of using medications like creams or ointments
 - This failure of creams and ointments had to happen within the 6 months before the beginning of the study
- Those who had been treated with dupilumab or with other medications that work in the same way as abrocitinib were not allowed to take part in this study.

How was the JADE DARE study conducted?

- Participants were divided by chance into two groups:
 - One group (362 patients) received abrocitinib at a dose of 200 mg per day as tablets, and a **placebo** injection that looked like dupilumab every 2 weeks
 - The other group (365 patients) received dupilumab at a dose of 300 mg injected every 2 weeks into the thigh, abdomen, or upper arm, and placebo tablets that looked like abrocitinib every day

Placebo: an inactive treatment that looks the same as the test treatment and is given in the same way.



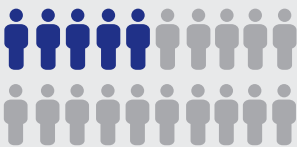
- The participants and the medical team members did not know which treatment individual participants received
- Throughout the study, once daily, all participants used medications like cream and ointments on skin patches with eczema
- Participants received treatment for 26 weeks and were observed for an additional 4 weeks
- Throughout the study, the medical team evaluated each participant for AD symptoms, such as itching, and visible AD signs, such as red or flaky skin
- The medical team also collected details of the participants’ health complaints

What did the JADE DARE study find?

- After 2 weeks of treatment, itching was notably improved in:



About **9** out of 20 patients receiving abrocitinib
172 out of 357 (48%)

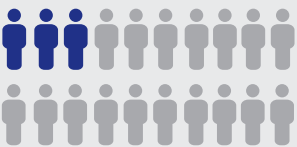


About **5** out of 20 patients receiving dupilumab
93 out of 364 (26%)

- After 4 weeks of treatment, eczema was mostly gone in:



About **6** out of 20 patients receiving abrocitinib
101 out of 357 (29%)



About **3** out of 20 patients receiving dupilumab
53 out of 364 (15%)

- After 16 weeks of treatment, eczema was mostly gone in:



About **11** out of 20 patients receiving abrocitinib
194 out of 357 (54%)



About **8** out of 20 patients receiving dupilumab
151 out of 360 (42%)

- Health complaints were reported in:



About **15** out of 20 patients receiving abrocitinib
268 out of 362 (74%)



About **13** out of 20 patients receiving dupilumab
239 out of 365 (65%)

Common health complaints were nausea, headache, acne, and conjunctivitis:

		Abrocitinib 200 mg (362 participants)	Dupilumab 300 mg (365 participants)
Feeling sick to the stomach (nausea)		19% 70 of 362	2% 8 of 365
Headache		13% 47 of 362	7% 24 of 365
Acne		13% 48 of 362	3% 11 of 365
Pink eye (conjunctivitis)		3% 10 of 362	11% 39 of 365

- Serious health complaints, which means those that were life-threatening or fatal, or required the participant's hospitalization, or resulted in permanent disability of the participant, were reported in 6 patients in each group:



About **1** out of 50 patients receiving abrocitinib

6 out of 362 (2%)



About **1** out of 50 patients receiving dupilumab

6 out of 365 (2%)

- Serious health complaints reported by the 6 patients taking abrocitinib were as follows:
 - Pneumonia
 - COVID-19 that led to pneumonia
 - Swelling of the gallbladder
 - Fracture of the arm
 - COVID-19 infection that resulted in death of the participant
 - Heart attack and stroke that resulted in death of the participant
- Serious health complaints reported by the 6 patients taking dupilumab were as follows:
 - Kidney problems
 - Worsening of asthma
 - Chest pain
 - Muscle tissue breakdown
 - Worsening of AD
 - Increased levels of a molecule in the blood that suggests liver problems

What do the results of the JADE DARE study mean?

- Among adults with moderate or severe AD that did not improve after treatment with prescribed medications like creams or ointments, 26 weeks of treatment with abrocitinib tablets improved the visible skin signs and itching symptoms of AD
- After 2 weeks of treatment, abrocitinib was better than dupilumab in improving itching
- After 4 and 16 weeks of treatment, abrocitinib was better than dupilumab in reducing most visible skin signs of AD
- Both abrocitinib and dupilumab are well tolerated over 26 weeks
- Together, the findings of the JADE DARE study demonstrate that more patients with moderate to severe AD experienced quick improvement in itchiness and eczema with abrocitinib than with dupilumab

Where can readers find more information?

The clinical trial included in this analysis is NCT04345367.

More information on this study can be found by entering the study number into the search field at www.clinicaltrials.gov

For more information on clinical studies in general, please visit <https://www.clinicaltrials.gov/ct2/about-studies/learn>

More information on living with AD can be found at:

<https://www.mayoclinic.org/living-better-with-atopic-dermatitis-eczema/scs-20515217>

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Who sponsored this study?

The JADE DARE study was sponsored by Pfizer Inc (the manufacturer of abrocitinib). Sponsoring means that Pfizer Inc designed the study, by working together with the government (for example, with the US Food and Drug Administration) and experts in AD. Pfizer Inc also organized the study and paid the expenses needed for the study's conduct.

Disclaimer

The medicine that was tested in this study, abrocitinib, is approved in some geographic regions for treating people with moderate-to-severe atopic dermatitis, for example, in North America, Europe, and Japan. The results of this study may differ from those of other studies. Healthcare providers should make treatment decisions based on all available evidence, not on the results of any single study.