Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medication works, how it works, and if it is safe to prescribe to study participants. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine(s) Studied: EUCRISA®/STAQUIS® (crisaborole)

Protocol Number: C3291032

Dates of Study: 27 July 2020 to 08 September 2021

Title of this Study: Study Comparing Use of Crisaborole Ointment With Vehicle Ointment (No Crisaborole) in Children and Adults With Mild to Moderate Atopic Dermatitis [A Phase 3, Multicenter, Randomized, Double Blind, Vehicle Controlled Study of the Efficacy and Safety of Crisaborole Ointment, 2% in Chinese and Japanese Pediatric and Adult Subjects (Ages 2 Years and Older) With Mild to Moderate Atopic Dermatitis]

Date(s) of this Report: 04 March 2022

– Thank You –

If you or your child participated in this study, Pfizer, the Sponsor, would like to thank you or your child for your participation.

This summary will describe the study results. If you or your child have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is atopic dermatitis?

Atopic dermatitis is a common skin condition that can cause many symptoms, such as itching, redness, and a rash that is scaling or oozing. The symptoms can look different on different people. Atopic dermatitis is also known as eczema. People with atopic dermatitis often have this condition for many years, and may have "flare ups", when their symptoms worsen for a time.

What is crisaborole?

Crisaborole is a medicine that is used to treat atopic dermatitis. It is applied to the skin as an ointment twice a day. Crisaborole may improve symptoms of atopic dermatitis by decreasing inflammation in the skin. Inflammation is the body's immune system response, which can lead to symptoms such as redness.

What was the purpose of this study?

The purpose of the study was to see if the symptoms of mild to moderate atopic dermatitis were reduced when crisaborole ointment was applied twice a day to the affected area compared to when a vehicle ointment was used. The vehicle ointment does not have any medicine in it, but it looks and feels just like the crisaborole ointment.

Crisaborole is a licensed treatment for atopic dermatitis in adults and children in some countries (United States, Canada, China, Israel, and Australia). This study was conducted in China and Japan to allow data to be collected in these countries.

Researchers wanted to know:

Did the symptoms of atopic dermatitis in adults and children 2 years and older reduce in areas of skin treated with crisaborole, and did the condition get better compared to areas of skin treated with vehicle ointment?

What happened during the study?

How was the study done?

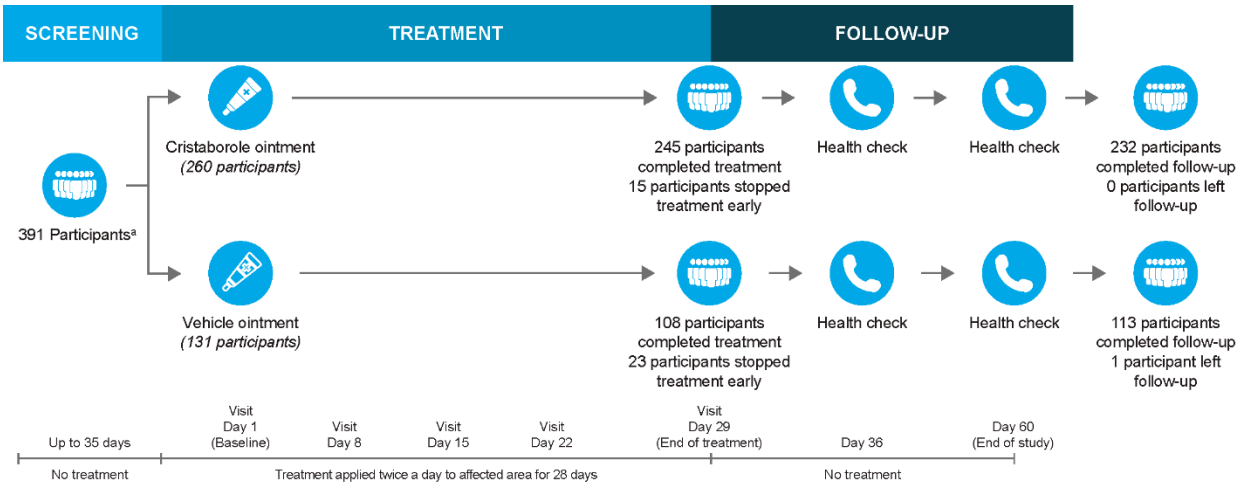
Researchers tested crisaborole ointment on adults and children 2 years and older in China and Japan to find out if participants who were treated with crisaborole had fewer symptoms of mild to moderate atopic dermatitis compared to participants who used a vehicle ointment.

Participants went to the study center to be screened by the study doctor to make sure they were able to join the study. This was known as the "screening period" and this lasted up to 35 days. Participants then entered the treatment period, which started on Day 1 and lasted 28 days. During the treatment period, participants (or their parents or caregivers if the participant was a child) were to apply the ointment twice a day to an area or areas of skin affected by the atopic dermatitis. Treatment was to be continued even if the participant had no symptoms of atopic dermatitis.

The study participants and researchers did not know who used the crisaborole ointment and who used the vehicle ointment. The study staff who looked at the participant's skin to assess how the treatment was working also did not know what treatment each participant had been given. This is known as an "double-blinded" study. Study participants were assigned to treatment with crisaborole ointment or vehicle ointment by chance alone. This was done to make sure that the study results were not influenced in any way.

Each participant visited the study center on Day 1, Day 8, Day 15, Day 22, and Day 29 for the study doctors to assess their atopic dermatitis and their general health. Participants were not treated on or after Day 29 but were to remain in the study until Day 60. Participants then received a follow-up telephone call on Day 36 and on Day 60 (or a month after their last treatment if the participant stopped treatment early). This telephone call was to check for any medical problems. This was considered the end of the study.

The following figure shows what happened during this study.



a 418 participants were screened and of these, 391 participants entered the study and were treated with cristaborole ointment or the vehicle ointment

Where did this study take place?

The Sponsor ran this study at 38 locations in China and Japan.

When did this study take place?

It began on 27 July 2020 and ended on 08 September 2021.

Who participated in this study?

The study included participants who had mild to moderate atopic dermatitis and were adults or children 2 years and older.

- A total of 205 men and boys participated
- A total of 186 women and girls participated
- All participants were between the ages of 2 and 71 years.

Participants were to be treated for 28 days. Of the 391 participants who were treated with crisaborole or vehicle ointment, 353 out of the 391 participants, or 90%, finished study treatment. There were 345 out of the 391 participants, or 88%, who finished the follow-up part of the study (some of these participants stopped treatment early while others completed the study treatment part).

There were 38 participants (38 out of 391, or 10%) who did not finish treatment with crisaborole or vehicle ointment because of:

- Medical problems (20 participants [5%])
- Lack of an effect (9 participants [2%])
- The participant or their parent or guardian wanted to stop treatment (6 participants [2%] and 2 participants [1%], respectively), or
- The doctor decided this was best for the participant (1 participant [less than 1%]).

There was 1 participant (1 out of 391, or less than 1%) who entered the follow-up phase of the study but who did not complete the follow-up part of the study. The study site tried to contact this participant but was not able to do so.

How long did the study last?

Study participants were in the study for about 3 months. The entire study took around 13½ months to complete.

When the study ended in September 2021, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

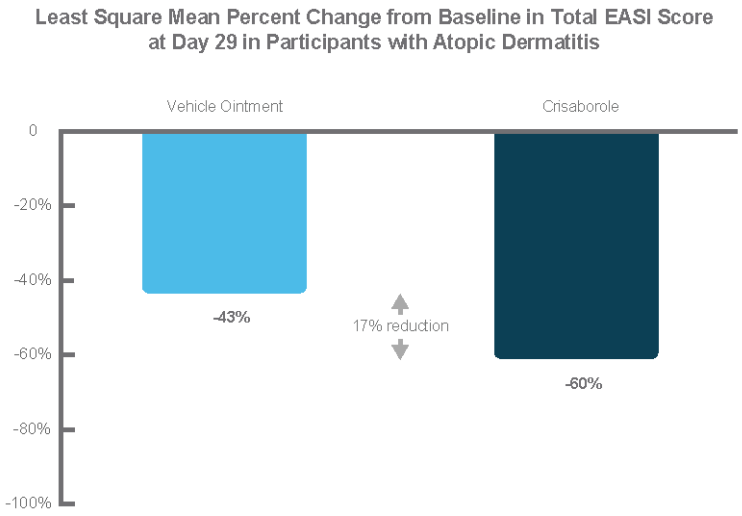
What were the results of the study?

Did the symptoms of atopic dermatitis in adults and children 2 years and older reduce in areas of skin treated with crisaborole, and did the condition improve compared to areas of skin treated with vehicle ointment?

To answer this question, the researchers used a clinical tool to rate the severity of symptoms of atopic dermatitis. This tool is called the Eczema Area and Severity Index or EASI. The researchers compared the severity of symptoms from before participants started treatment to Day 29. This gave the researchers the least square mean percent change in EASI score from the start of the study on Day 1 to Day 29. Least square mean is a special way of calculating the average in certain types of statistical analysis. The least square mean percent change in EASI score from Baseline to Day 29 tells the researchers how the participant's atopic dermatitis had changed after 28 days of treatment in this study.

Did crisaborole help to improve the symptoms of atopic dermatitis compared to vehicle ointment?

On average, participants who used crisaborole had a least square mean percent decrease in total EASI score at Day 29 of 60% compared to 43% in participants who used the vehicle ointment.



Based on these results, the researchers have decided that these are not likely the result of chance. The study medication may help improve the symptoms of atopic dermatitis.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors try to understand what effects a study medication might have on a participant.

A total of 178 out of 391 (46%) participants in this study had at least 1 medical problem. There was 20 out of the 391 participants, or 5%, who stopped using the study medication permanently or left the study because of medical problems. The most common medical problems – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by 8 or more participants are listed.
- The **2nd** column tells how many of the 260 participants using crisaborole ointment reported each medical problem. Next to this number is the percentage of the 260 participants using crisaborole ointment who reported the medical problem.
- The **3rd** column tells how many of the 131 participants using the vehicle ointment reported each medical problem. Next to this number is the percentage of the 131 participants using the vehicle ointment who reported the medical problem.
- Using these instructions, you can see that 34 out of the 260 (13%) participants using crisaborole ointment reported pain where the ointment was applied. A total of 5 out of the 131 (4%) participants using the vehicle ointment reported pain where the ointment was applied.

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**Crisaborole Ointment (260 Participants)**	**Vehicle Ointment (131 Participants)**
Pain where the treatment was applied	34 out of 260 participants (13%)	5 out of 131 participants (4%)
Atopic dermatitis	20 out of 260 participants (8%)	15 out of 131 participants (11%)
Infection of one or more of the pockets from which hair grows (follicles)	8 out of 260 participants (3%)	6 out of 131 participants (5%)
Infection of the nose and throat or cold (nasopharyngitis)	9 out of 260 participants (3%)	4 out of 131 participants (3%)
Common cold (upper respiratory tract infection)	9 out of 260 participants (3%)	4 out of 131 participants (3%)
Change in skin color where treatment was applied	9 out of 260 participants (3%)	1 out of 131 participants (1%)

Did study participants have any serious medical problems?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems.

Two (2) participants (1%, or 2 out of 391 participants) had serious medical problems.

- One (1) participant using the crisaborole ointment had carpel tunnel syndrome that worsened. Carpel tunnel syndrome is a condition that causes pain, tingling, and numbness in the hands and fingers. This serious medical problem happened just after treatment had finished and the participant got better. The doctor and the researcher did not think this was related to the study ointment.
- One (1) participant using the vehicle ointment had a laboratory test result that showed higher than normal levels of a heart protein in the blood. This suggested there was some damage to the heart. This serious medical problem happened after treatment had finished and the participant got better. The doctor and the researcher did not think this was related to the study ointment.

No participants died during the study.

Where can I learn more about this study?

If you have questions about the results of the study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.clinicaltrials.gov
Use the study identifier **NCT04360187**

www.pfizer.com/research/research_clinical_trials/trial_results
Use the protocol number **C3291032**

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for study participants.

Again, if you or your child participated in this study, **thank you** for volunteering. We do research to try to find the best ways to help study participants, and you or your child helped us to do that!