Clinical Study Results

Research sponsor: AstraZeneca AB

Drug studied: Pain relief patch

Study title: A study to learn if a pain relief patch reduces injection site pain in healthy volunteers as well as an approved patch

Thank you!

Thank you to the participants who took part in the clinical trial for a pain relief patch.

AstraZeneca AB sponsored this study and thinks it is important to share the results. An independent, non-profit organization called CISCRP helped prepare this summary of the study results for you.

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

What is happening with the study now?

The study started in October 2017 and ended in November 2017. The study included 32 participants in Germany.

The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

Why was the research needed?

Researchers are looking for a better way to reduce pain in people when they get an injection. Before a treatment can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

The researchers in this study wanted to learn more about a pain relief patch that may reduce the pain that people feel when they get an injection. Doctors sometimes use pain relief patches to numb part of a patient's body. This can help reduce the pain from the injection.

The researchers in this study wanted to compare the study pain relief patch to another pain relief patch that had already been approved. They wanted to know if the study patch worked as well as the approved patch. Both patches contained the same combination of drugs and the same amount of each drug. But, the patches were made by different companies. They also wanted to find out if the participants had any medical problems during the study.

The main questions the researchers wanted to answer in this study were:

- Did the study patch reduce injection site pain in participants as well as the approved patch?
- What medical problems did the participants have during the study?

The researchers asked for the help of healthy men and women. Everyone in the study was 22 to 57 years old when they joined.

What kind of study was this?

This was a “double-blind” study. This means none of the participants or the researchers knew which treatment the participants got. Some studies are done this way because knowing what treatment the participants are getting can affect the results of the study. When the study ended, the research sponsor found out which treatment participants got so they could create a report of the study results.

There were 3 patches tested in the study:

- the study patch
- the approved patch
- a placebo patch

A placebo patch looks like the study patch but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the treatment are actually caused by the treatment.

This was also a “crossover” study. This means that each participant got all of the study treatments, but in a different order.

A computer program was used to randomly choose the treatment order each participant got. This helps make sure the groups are chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

What happened during the study?

At the beginning of the study, the doctors:

- did a physical examination of the participants' hands
- asked about the medical history of participants, how they were feeling, and what medicines they were taking

If the participants were healthy enough to join the study, the doctors applied 1 patch to the back of each hand at the same time during this visit. Participants got 1 of the 2 treatments below:

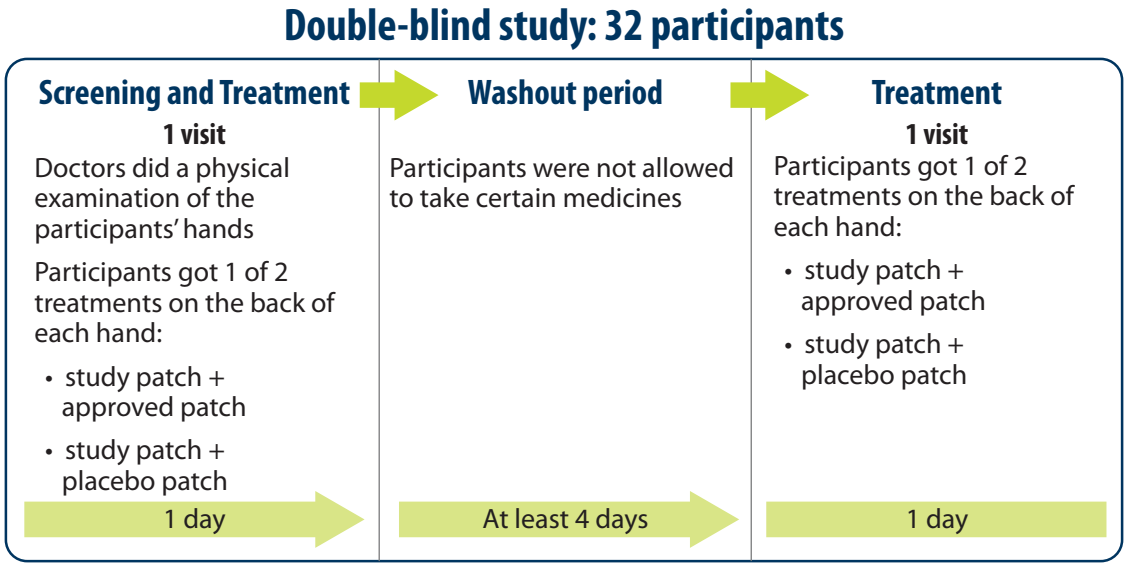
- the study patch and the approved patch
- the study patch and the placebo patch

After treatment with the patches, the doctors gave the participants a placebo injection on each hand where they had applied the patches. A placebo injection does not have any medicine in it.

After this visit, the participants later visited their study site 1 more time and got the patch treatment that they did not get at the first visit. At the second visit, the participants got the study patch on the hand that did not get the study patch at the first visit. The participants got another placebo injection on each hand where the doctors had applied the patches.

There was a "washout period" of at least 4 days in between the 2 visits. During this time, the participants were not allowed to take certain medicines. This means that their bodies processed all of the medicines in their blood, and the study medicines had "washed out" of their bodies.

The graphic below shows how the study was done.



What were the results of the study?

This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment change.

The websites listed at the end of this summary may have a full report of the study results.

Did the patch reduce injection site pain in participants as well as the approved patch?

In general, the researchers found that the study patch reduced the participants' average injection site pain in a similar amount compared to the approved patch.

To answer this question, the researchers asked the participants to rate their injection site pain after each injection. Participants rated their pain on a scale from 0 to 100. Zero meant no injection site pain, and 100 meant the highest amount of injection site pain.

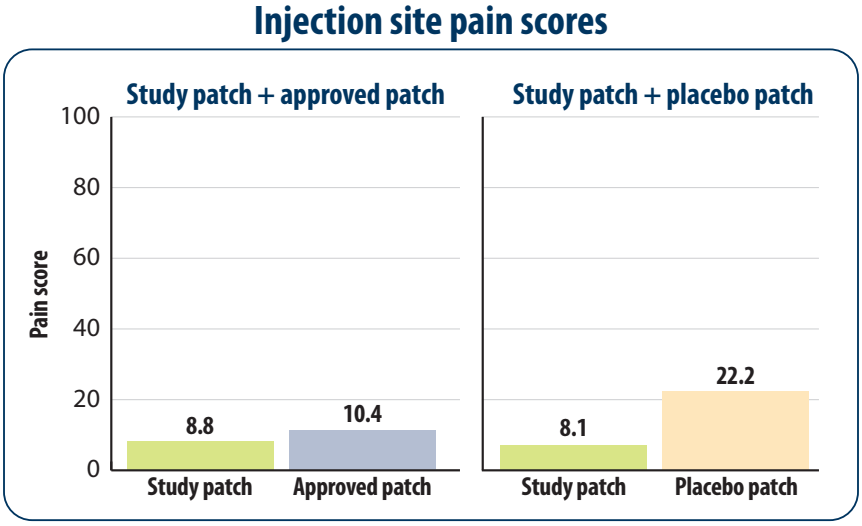
When the participants got the study patch and the approved patch treatment:

- on average, the participants rated their pain as an 8.8 after getting the study patch
- on average, the participants rated their pain as a 10.4 after getting the approved patch

When the participants got the study patch and the placebo patch treatment:

- on average, the participants rated their pain as an 8.1 after getting the study patch
- on average, the participants rated their pain as a 22.2 after getting the placebo patch

The chart below shows these results.



What medical problems did the participants have during the study?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the study treatments. These medical problems are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

These adverse reactions may or may not be caused by the study treatments. A lot of research is needed to know whether a treatment causes an adverse reaction. The websites listed at the end of this summary may have more information about the adverse reactions or other medical problems that happened in this study.

How many participants had serious adverse reactions?

None of the participants had serious adverse reactions during the study. None of the participants died during the study.

How many participants had adverse reactions?

None of the participants had adverse reactions during the study. None of the participants stopped taking the study treatments because of adverse reactions they had during the study.

How has this study helped patients and researchers?

These results helped the researchers compare the study pain relief patch to an approved pain relief patch for reducing injection site pain.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies with the study pain relief patch are not planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. If a full report of the study results is available, it also can be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03313336"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D069GC00001"** into the search box and click **"Find a Study"**.

Full trial title: A Double-blind, Randomized, 2-Period, Placebo-controlled, Single-center, Crossover Study to Assess the Therapeutic Equivalence of the EMLA Current Reference Patch and the EMLA Test Patch in Healthy Subjects

AstraZeneca Protocol number: D069GC00001

AstraZeneca AB sponsored this study and has its headquarters in Södertälje, Sweden.

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

Thank you!

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for participants.