

## MEDICAL RESEARCH STUDIES

Before any drug is made available to the public, it must be tested carefully in medical research studies, also known as clinical trials. These studies are conducted to make sure an investigational medication is safe and effective. Not until results from multiple clinical trials demonstrate an investigational medication's effectiveness and safety can a pharmaceutical company apply for governmental approval. If the drug is approved, then the pharmaceutical company can make their medication available to the public.

Medical research studies follow a detailed study plan called a protocol. The protocol is reviewed and approved by an independent review board (IRB) comprised of doctors, scientists, and community members not affiliated with the company sponsoring the research. The IRB's job is to ensure that the study is well designed and includes safety precautions to protect all study participants.

Participation in this study could help researchers learn more about treating ankle sprain pain. However, your participation is completely voluntary. You may stop participation in the study at any time. In addition, your study staff is required to provide you with complete answers to any questions you may have.

To learn more, please contact:

Knocked off  
your game by an  
**ANKLE  
SPRAIN?**



Local doctors need  
teens who have  
sprained an ankle in the  
last 24 hours to help test  
the effectiveness  
of an investigational  
pain-relieving patch  
that's applied directly  
to the ankle.

# Recently SPRAINED YOUR ANKLE?

## Consider this study.

The pain you experience from an ankle sprain can not only inconvenience you and your family, it can also have a big impact on your normal, daily life. Missing school events and other extracurricular activities because of the pain can become extremely frustrating and cause unwanted stress in your life. Although there are current medications available to help with the pain, they often take time to work through your body and aren't always effective for everyone. As a result, more treatment options are still needed today to help treat the pain associated with an ankle sprain.

Local doctors are currently conducting a clinical research study evaluating the effectiveness and safety of investigational, medicated patches for treating the pain associated with an ankle sprain, when placed directly on the site of the ankle pain.

### What is the purpose of this study?

The purpose of this study is to help researchers learn more about the effectiveness and safety of investigational, medicated patches, when applied directly to the sprained ankle, at the site of the pain. This study is specifically evaluating the investigational, medicated patches when used by adolescent participants who have sprained their ankle within the past 24 hours.

### What's important to know about the investigational patches?

The investigational, medicated patches being tested in this study contain some of the same active ingredients that are in currently approved pain-relieving patches (known as Salonpas®), which are available over the counter for relief of minor aches and pains of the muscles and joints. The investigational patches have been evaluated in previous muscle strain studies, with positive outcomes. Based on the results from one of these studies, the United States Food and Drug Administration (FDA) has already approved these investigational patches to be marketed to adults.

Because these medicated patches have not yet been approved for use with adolescents, they are still considered investigational for the purposes of this study. There have already been other studies conducted using the investigational, medicated patches in adolescent participants.

### Would I be eligible to participate in this study?

To pre-qualify for this study, you must be:

- 13 to 17 years of age,
- Experiencing pain from an ankle sprain that has occurred **within the last 24 hours**,
- Willing to stay at the study clinic for 12 to 14 hours, AND
- Able to bear weight on your sprained ankle.

Qualified participants will receive study-related medical evaluations and study patches at no cost. Reimbursement for time and travel may also be provided.

### What happens during the study?

If you are eligible and you decide to participate in this study, your total participation will last four days, with approximately three visits to the study clinic. During the clinic visits, you will undergo a series of medical tests and assessments to monitor your safety and progress.

These will include, but not be limited to:

- Vital sign measurements (blood pressure, heart rate, temperature),
- Physical examinations,
- Review of your medical history,
- Assessments of your ankle sprain and pain level,
- Skin observations and assessments, and
- Blood and urine samples.

In addition, female participants who are able to have children will be given a pregnancy test. You will not be allowed to participate in this study if you are pregnant or breast feeding.

At the beginning of the study, you will be randomly assigned (like the flip of a coin) to one of two treatment groups:

- Group 1 participants will receive treatment with the active study patches
- Group 2 participants will receive treatment with placebo study patches (patches that look like the investigational, medicated patches but do not contain any active drug)

You will have a 50% chance of being assigned to either treatment group. This study is double-blinded, which means neither you nor your study doctor will know which treatment group you are assigned. The study is designed this way to ensure that any feelings you or your doctor have about the active or placebo study patches will not affect study results. If your study doctor needs this information for emergency purposes, however, he/she will be provided access.

At all times during this study, if your ankle sprain pain becomes unbearable, you will have the choice to take acetaminophen (Tylenol®) as "rescue" medication.

### Are there any risks or benefits to me as a study participant?

As with any clinical research study, there are possible risks associated with participation. While the investigational, medicated patches are being evaluated for their effectiveness and safety in treating ankle pain associated with your sprain, it is possible that your condition could become worse. You could experience side effects. The side effects could be ones that are common and previously seen before (redness, rash, and/or itching where the patches are applied), or they could be side effects that have not been seen before.

Of course, it is also possible that you may benefit by participating in this study, although this cannot be guaranteed.

### What if I have questions?

If you have any questions about the investigational patches or about this study in general, please speak with your study doctor.