Consent to Participate in a Research Study

Legs vs Back: Patient experience and quality of patch testing for allergic contact dermatitis

The purpose of this from is to give you or your legally authorized representative (LAR) basic information about a research study. As you or your LAR read these pages, feel free to ask questions. Being a part of this study is your choice, so please think about the information carefully. If you or your LAR choose to be a part of the study, your or your LAR can sign a consent, or agreement, at the end of these pages.

1. INVESTIGATOR(S) CONDUCTING THIS STUDY

Who will be in charge of this study?

Caroline Brumley, BS, Contact Dermatitis Fellow, Park Nicollet Contact Dermatitis Clinic, 7550 34th Ave S, Minneapolis, MN 55450

Sara Hylwa, MD, Faculty Physician, Department of Dermatology, Park Nicollet Contact Dermatitis Clinic, 7550 34th Ave S, Minneapolis, MN 55450

2. SOURCE OF SUPPORT

Who is funding this research study?

The Park Nicollet Contact Dermatitis Clinic received a grant from the American Contact Dermatitis Society to support this research. The study investigators have no financial conflicts of interest.

3. SITE OF THE RESEARCH STUDY

Where will this study be done?

This research study will be done at the Park Nicollet Contact Dermatitis Clinic in Minneapolis, MN. Up to 60 patients will be enrolled.

4. PURPOSE OF THIS RESEARCH STUDY

Why is this research study being done?

The purpose of this study is to determine if putting the patches on your legs or your back would provide a more comfortable experience during your patch testing. Patch testing is most often done on the back, but we are interested to know if placing them on the legs creates a better user experience while still obtaining high quality testing results.

5. ELIGIBLITY

Who is being asked to be a part of this research study?

You are being asked to be a part of this study because you are currently scheduled to undergo patch testing.

In order to participate in this study, you must meet the following criteria:

- Age 18 years or older
- Both your back and thighs are clear and able to be used for patch testing
    a. i.e. no large tattoos, no rash, large enough space
- Signed and witnessed written informed consent
- Willingness to comply with the study protocol

You will NOT be able to participate in this study if you meet any of these criteria:

- Age 17 or younger
- You are pregnant or breastfeeding
- You are undergoing specialized patch testing with fewer than 90 patches applied
- Rash, large tattoos, or limited space on the thighs and/or back
- You have specific needs that require the use of your thighs or back (ex. You need to attend an event, etc.)

6. PROCEDURES

What procedures will be done for this research study?

If you agree to participate in this study, you will receive patch testing, which occurs over three visits to the clinic. You will have already committed to all three appointments over the course of 5 days along the proper timeline. You must comply with all necessary rules to ensure that the patch tests are not compromised during testing. Study tasks will include a survey and assessment of patches by a study coordinator during your second patch testing visit of the week. The last visit of your test week will proceed as normal without any further study activities.

What is patch testing?

Patch test is a well-defined medical testing procedure (i.e. not experimental) that is done to check for allergies to certain ingredients in products. During a patch test, small metal circles dotted with chemicals are taped to the skin.

How is patch testing performed?

During the first visit, the patches will be applied to your upper back and taped in place. The patch tests are metal circles (patches) that have a small amount of allergen on them that are taped to the back (or arms) and must remain in place for 48 hours. After the 48 hours, you will return to the dermatology clinic and the doctor will remove the patches and look for any reactions. You will return to the clinic again two days later for a final reading by the doctor.

How do I care for my patches during the course of testing?

You must try to keep the entire patch areas dry during the testing period, the two days when the patches are taped to your legs or back, and the following two days. This means that you cannot

shower for the entire five days. However, you may sponge bathe all areas of your body except your back or legs. Be careful shampooing your hair so you do not splash water on your back or legs.

You may also not take part in any strenuous activities during the test. You must also avoid any activities that make you sweat or use vigorous arm movements as these may loosen the patches.

What will the treatments be like?

The first two days while the allergens are taped in place on your back or back can be a little uncomfortable and itchy at times. You will be restricted in your movements because of this tape, but you can sit, stand, walk, and sleep on your back or sides.

For patch testing, we are looking to see if small "itchy spots" develop on your back, so it is not uncommon to get itching underneath the patches at this time. Unfortunately, you are unable to scratch or rub the patches as this can interfere with the testing. You are allowed to take antihistamines, such as Claritin, Allegra, Zyrtec, or Benadryl to help with the itching if you have no other medical reason to not take these medications.

After 48 hours, the patches are removed, and a reading is done. At this time, you will complete a survey and a study coordinator will assess your patches. This concludes the study activities. You may still continue to develop "itchy spots" between the 48 and 96 hour test. You still cannot itch or scratch them, but you can apply a cold pack wrapped in a towel if the itching is bothering you.

At the final visit, all the tape is removed and the final patch test interpretation is done. At this point, you are able to scratch any itches if needed as well as shower / take a bath.

How long will each appointment last?

Expect the first visit to take approximately 60-90 minutes, the second visit 30-45 minutes, the last visit 30-60 minutes. Study activities will take approximately 20 additional minutes on the day of your second visit.

What are the instructions that I will receive?

Patch Test Instructions

Patch tests are done to check for allergies to certain chemicals. During a patch test, small metal circles dotted with chemicals are taped to the skin.

The metal circles (patches) will remain in place for 48 hours. At that time, you will return to the dermatology clinic and the doctor will remove the patches and look for any reactions. You will return to the clinic again two days later for a final reading by the doctor.

This sheet will tell you how to take care of the patches during the test.

Care While Wearing Patches

Keep the entire patch areas dry during the testing period, the two days when the patches are taped to your arms, and the following two days. Do not shower for the entire five days. You may sponge bathe all areas of your body except your back and/or arms. Be careful shampooing your hair so you do not splash water on your back and/or arms.

Do not take part in any strenuous activities during the test. Avoid any activities that make you sweat or use vigorous arm movements. These may loosen the patches.

If you are a female, you will not be able to wear a bra for between the first and second visits.

We recommend that you do not sleep on your stomach during the patches but rather on your back or side in order to not hasten the loosening of the patches.

Problems

If any of the patches fall off, call the dermatology clinic. The phone number is (952) 977-3450. If a patch falls off after clinic hours, please call the next day.

If a strip of tests loosens so that the metal circles are not touching your skin, do not replace the patches. Remove the loose strip, noting the day and time. It will also help if you write down any reactions you notice as the tape is removed. Circle any reddened or blistered areas with a ballpoint pen.

A positive reaction and/or having tape on your back may cause mild discomfort and itching. This is normal. However, if you feel severe burning or itching that you cannot tolerate, remove the patch at once. You may have someone cut off that particular patch.

You should not take oral prednisone during the test period or have had a recent cortisone injection, as this will interfere with the test results.

Follow-up Appointment

You will return to the clinic to have the skin patches read 48 and 96 hours after they were put on.

After the patches are removed, you will have to wait 30 minutes before the area can be read. If you had to remove a patch, be sure to tell the doctor or nurse.
Your doctor will tell you the results of the test and what treatment you will need.

If you develop a patch of rough, red, scaly skin at any of the test sites within three weeks after your patch test reading, call the clinic and speak to one of the nurses or to your doctor.

If you have any questions or problems, call the contact dermatitis clinic at (952) 977-3450.

7. RISKS, DISCOMFORTS, AND INCONVENIENCES

What are the possible risks, side effects, discomforts, or inconveniences of this research?

The most common discomfort is discomfort from the tape and restriction of movement. Many people find it inconvenient that they cannot take a complete shower or bath over the course of the 5 days of testing, although you are allowed to take a sponge bath during this time. Itching that may develop over the course of the testing is also uncomfortable at times.

The side effects of patch testing include becoming allergic to a substance during the course of patch testing, developing itching reactions and rashes under the area of patch testing and sometimes at distant sites during or just after the course of testing. Sometimes the reactions may be blistering, last for several weeks after the completion of testing, or cause the skin to be temporarily or permanently discolored under the areas of patch testing, although these are quite uncommon.

The inconveniences include (in addition to the above) that you must attend the three visits in our clinic over the course of 5 days. Testing activities will only take place during the first two visits.

8. REPRODUCTIVE AND PREGNANCY ISSUES

What is important to know about being a part of this study and pregnancy?

If you are pregnant or breastfeeding, you will not be eligible to participate in this study.

9. HEALTH BENEFITS

What are the possible health benefits to you or others from your being part of this research study?

You are taking part in this study alongside your already scheduled patch testing to which you have been referred by your dermatologist or allergist. Therefore, you will be receiving important answers about your skin condition. In addition, by participating in the study, you will help us make the patch testing process as comfortable as possible for future patients. We will also try to understand if the location of patches does not have an effect on the quality of testing.

10. ALTERNATIVE TREATMENTS

What treatments or procedures are there for you if you decide not to be part of this research study?

You do not have to be in this study. There is a standard of care for allergic contact dermatitis, and you will receive this care even if you do not participate in this study.

11. CONFIDENTIALITY

Who will know that you are part of this research study?

Any information that could be used to identify you will be treated with strict confidence to the extent allowed by law. Nevertheless, some uses and disclosures of your information are

necessary to conduct the study. If you agree to be part of this study, you will be also allowing the use and disclosures of your private health information as needed for the purpose of this study as described in this consent.

"Private health information" means information that identifies you and is collected during this study.

By signing this consent, you are agreeing that your private health information may be disclosed and used by:

- The doctors and other health care professionals involved in this study
- Their staff
- The research center (Health Partners Institute)
- The HealthPartners Institute Institutional Review Board
- Monitors from the United States Government and/or the Food and Drug Administration (FDA).

The findings of this study may be used for scientific meetings, written reports, and publication, but no information that could be used to identify you will be disclosed for these purposes.

Once your private health information has been disclosed to a third party, federal privacy laws may no longer protect it from re-disclosure. However, anyone obtaining access to your private health information under this consent must agree to protect your information as required by this consent.

This consent to use your private health information as described above does not expire. However, if you later change your mind, you can revoke this consent by writing to Dr. Sara Hylwa or Caroline Brumley, saying that you no longer wish to allow your private health information to be used for this study. If you revoke your consent, you may no longer be able to participate in this study. Moreover, we cannot undo uses or disclosures of your private health information that have already taken place in reliance on your prior consent.

12. COSTS ASSOCIATED WITH THE RESEARCH STUDY

Will your insurance provider or you be billed for any costs of any treatments, medicines, or procedures done as part of this study?

You will be billed as is standard for patch testing. There will be no additional costs for taking part in this study.

13. COMPENSATION AND MEDICAL TREATMENT FOR ANY STUDY-RELATED INJURY

If you are injured from being part of this research study, what should you do and who will pay for it?

If you agree to be a part of this study and believe you are sick or have been injured from being in this study, you should – depending on the degree that you are ill – seek care for your illness or injury and when possible contact the study researcher, Dr. Sara Hylwa (952-977-3450) or

Caroline Brumley (bruml061@umn.edu) day or night. Financial compensation for lost wages, disability, and/or discomfort is not available. The cost of this medical care will be billed to you or your insurance company.

14. COMPENSATION FOR PARTICIPATION

Wil you be paid for being part of this research study?

There will be no compensation for participation in this research study.

15. NEW FINDINGS

Will you be told of any new information of new risks that may be found while this study is going on?

In every research study, there may be risks we do not expect. Patch testing has been performed for a long-time. Nevertheless, you will be told about any important new information that may cause you to change your mind about being a part of this study.

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

16. FREEDOM TO PARTICPATE AND WITHDRAW

Is being part of this research study voluntary?

Yes, being part of this research study is your choice.

Can you decide to stop being in this research study at any time?

Yes, you do not have to be a part of this study. You can agree to be in the study now and change your mind later. Your decision to stop participating in the study will not affect your regular care and will have no legal impact. Your doctor's attitude towards you will not change.

17. PROCEDURES FOR ORDERLY WITHDRAWAL OR REMOVAL FROM THE STUDY

What would happen if you decide to stop being part of this study or if you are removed from this study?

Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time.

Your regular medical care at this study center will not change if you decide to not be in this study. If you want to stop being in this study, tell the study doctor or study staff.

The study doctor can remove you from the study at any time, even if you want to stay in this study. This could happen if:

- The study doctor believes it is best for you to stop being in the study
- Your do not follow the directions of the study
- The study ends

If you stop being in the study early, the study doctor or the study staff may ask you some questions about being in the study.

18. CONTACT INFORMATION FOR QUESTIONS

Who should you contact if you have questions?

If you have any problems, concerns, or questions about the study or your rights as a subject in this research study, want to obtain information, or want to offer input, and want to talk to someone other than the study doctor, please contact the Research Subjects Protection Program Office at 952-967-5025 or Amy.A.Fehrer@HealthPartners.Com.

If you have any questions before signing this consent, be sure to ask them now. During the study, if you have any questions, concerns, or complaints for the study doctor, please contact Caroline Brumley (bruml061@umn.edu) or Dr. Sara Hylwa (952- 977-3450).

Who oversees this study?

The HealthPartners Institute Institutional Review Board (IRB) has approved this study. The IRB is a committee of people who review all research studies at HealthPartners to check that they meet federal laws and ethical standards.

IRB approval only means it is ok for the study to begin. *Only you* can decide if being in this study is the right decision. Feel free to talk about this study with your family, friends, and personal doctor before you decide.

VOLUNTARY CONSENT FORM

- I have either read the attached consent or it has been read to me.
- By signing this form, I do not give up any of my legal rights or release anyone involved in this research study from their responsibility for negligence.
- By signing this form, I agree to be part of this research study and consent to the use of my private health information as described in Section 11 ("Confidentiality") of the attached consent.
- A signed copy of this consent form will be given to me.

Subject's / Legally Authorized Representative's Printed Name and Signature

Date

For Site Use only:

- I have carefully explained to the subject the nature and purpose of this study.
- The subject has been given enough time and an adequate place to read and review this form.
- The subject has had a chance to ask questions and receive answers about this study.
- I have explained and discussed the nature of the research.
- I have explained and discussed potential risks and benefits.
- The alternate treatments available to the subject and the benefits and risks of each

Name of person obtaining informed consent (print) Title Phone number

Signature of person obtaining informed consent