

About the Skin Biopsy Sub-Study

Thank you for choosing to participate in the [REDACTED] Trial! We are asking participants to consider joining an optional sub-study involving skin biopsies. The choice to participate in this optional sub-study will not impact your ability to participate in the [REDACTED] Trial overall.



What Is the Skin Biopsy Sub-Study?

This sub-study is an addition to the main [REDACTED] Trial. It will occur at the same time as the main trial and does not require any additional visits.

During the sub-study, the trial team will collect 3-millimeter sized samples of lupus-affected skin from participants to analyze in a lab. Choosing to join the sub-study is completely up to you, and you can change your mind at any time.

You may receive additional payment for biopsy procedures if you choose to participate.



Why Is the Sub-Study Being Done?

In the main [REDACTED] Trial, the trial team examines your skin to see how your lupus symptoms are doing and how the assigned trial pill may be affecting them. The information from these exams tells us a lot, but there is more to learn.

In the biopsy sub-study, a sample of skin will be collected from where you have symptoms. This will allow researchers to see the actual changes happening in the skin cells.

If you decide to join this sub-study, you will undergo 6 skin biopsies, 3 at the beginning of the treatment period and 3 at the end.



When Will the Biopsies Be Done?

The first 3 biopsies will be done at **Visit 2 (Day 1)**.

The remaining 3 biopsies will be done at **Visit 8 (Week 16)**.



Where Will the Biopsies Be Taken From?

The samples will be taken from an area on your skin where you experience lupus symptoms, such as a rash. The trial doctor will assess your affected skin carefully to find the best place to take a biopsy. They will do their best, when possible, to avoid locations that may be difficult to heal or leave unwanted scarring.

If you have any questions or concerns about the healing process and possible scarring, you can discuss them with your trial doctor to help decide if this sub-study is right for you.



What Are the Goals?

By evaluating a small sample of the skin, researchers can see a more detailed picture of how your skin symptoms are doing. The study team wants to:

- **See the before and after.** Compare your first biopsy sample to the second one to see how the skin may have changed
- **Track symptoms.** Look for improvements in inflammation and healing

This sub-study is completely optional. You may choose to join or withdraw at any time for any reason.



How Are the Biopsies Done and What Should I Expect?

The skin biopsy is a 10- to 15-minute-long procedure that will be performed by a trained trial doctor.

- The doctor will numb your skin and then use a tool to remove a small (3 millimeter) piece of skin.
- During the procedure, you may feel dull pressure or a pulling feeling. A small amount of bleeding may occur after the biopsy.
- You will be able to go home right after the procedure. You may experience some soreness or tenderness at the biopsy site after the numbing wears off.

Approximate sample size: ● (3 mm)

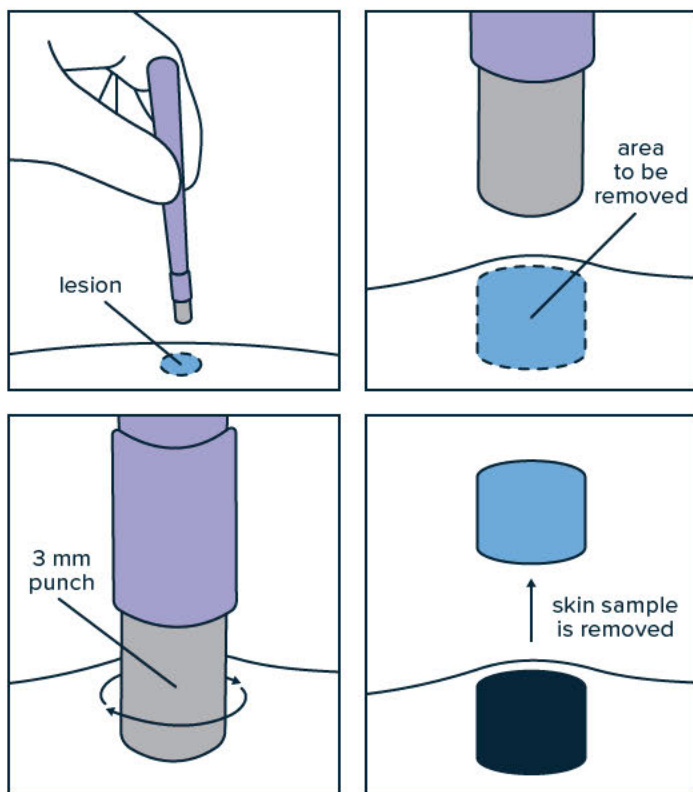


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What Is the Healing Process?

Your trial doctor will give you instructions to follow for taking care of your biopsy wound. You may have a small scar after the wound heals.



How Are Biopsy Samples Stored and Kept?

The trial doctor can give you information about how your biopsy samples will be stored. There is more information on how data is kept and protected in the Optional Skin Biopsy Sub-Study Informed Consent.

If you decide to leave the sub-study, you can request that any samples you provided be destroyed and not undergo any testing.

Thank you for considering this biopsy sub-study.
The information learned from this research will help to build our knowledge of the trial drug.