

The PossibLity Study

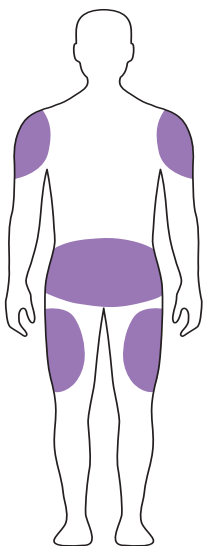


Medication Administration Guide

Introduction

Thank you for considering the PossibLity Study. We appreciate your willingness to contribute to important research on atopic dermatitis.

This information sheet explains the administration process of the study medication and blindfolding, the importance of blinding in clinical trials, and the measures we will take to ensure your comfort.



During the PossibLity Study, you will receive the investigational drug called galvokimig or a placebo every 2 weeks as 2 subcutaneous injections, ie, it will be injected with a needle under the skin. The injection will be on either your lower stomach area (belly/tummy), the outside of your upper thighs or your upper arm. The needle used for the injection is similar to a needle when the doctor draws blood from your arm for blood tests. You may feel an initial prick that normally quickly subsides.

The study medication injection takes place during visits to the study center. The injection process will take only a few seconds (between 10 to 20 seconds) per injection. During that time, you will be asked to wear a blindfold to prevent you from seeing the medication that you're getting. We understand that this might feel unusual, but it is a necessary step to ensure the data collected in the study remains objective and unbiased. This is part of a process called blinding.



Why is blinding important?

Blinding is crucial because it removes bias and ensures the reliability of clinical trial results. In a blinded study, neither the participant nor the study doctor knows which study treatment (investigational drug or placebo) the participant is receiving. This is called “double-blinding”. It is important that people involved in the evaluation of the study drug remain objective and that there is no undue influence of people’s expectations or preconceived notions about the study outcomes.

Is the PossiblLity study blinded?

The PossiblLity Study is a double-blinded study. A dedicated separate study team will be specifically involved in preparing and proceeding with the injections of the study medication. They will know what you are receiving but they will not be involved in any other assessment evaluating the efficacy or safety of the study medication.

Why is Blindfolding Necessary in the PossiblLity Study?

In the PossiblLity Study, because of the way that the investigational drug galvokimig is produced, the study medication and the placebo cannot be made to look exactly alike. This visual difference could potentially reveal which treatment you are receiving, which would compromise the blinding process. The syringes used to administer the medication may also look different.

For this reason, and to keep the integrity of the study and ensure that the data collected are accurate and unbiased, you will not be able to see the syringes used and will have to wear a blindfold during the treatment administration. The blindfold must be worn every time you receive the study medication injections, but it is only for a very short time (approx. 10 to 20 seconds). This blindfold is similar to the blindfold used in airplanes during overnight travels. You can ask the site personnel to try it on before the study medication administration starts so that you can get used to it.

How does the medication administration process work?

The injections will take place in a dedicated room. You will sit down and relax while the study staff make the last necessary arrangements prior to injections. The study staff will provide you with a single use blindfold to cover your eyes during the injections. You will not be allowed to see the syringes that will be covered until the last minute before injection. When the staff is ready, they will ask you to cover your eyes with the blindfold using the cord to fit it around your head.

If you prefer, you can ask the study staff to describe what they are doing while you are blinded such as “I am preparing the syringes”, “I am preparing the injection site by disinfecting it”, “I am ready to inject, it will take a few seconds, are you ready as well?” The process will be repeated for the second injection.

If you need to pause between injections, do let the study staff know so that they are prepared and can cover the second syringe during this time. The 2 injections will be completed in a maximum of 5 minutes. The study staff will take notes during the process to record the exact time and duration of the injections.

Your comfort is important to us

We are committed to making your experience as comfortable as possible. The study staff will guide you every step of the way while you are blindfolded. You can express your wishes about what would make you more comfortable in this unusual situation – be it verbal explanations of what is happening or perhaps soothing music or other distractions to help you relax during the brief period you are blindfolded.

Our goal is to minimize any discomfort or anxiety you might feel. The blindfolding process will be quick, and the study staff will be there to offer support and reassurance.

Thank you!

Blindfolding in the PossiblLity Study is an essential measure to ensure the accuracy and integrity of the research. We greatly appreciate your cooperation and will do everything we can to make your participation as pleasant and comfortable as possible.

If you have any questions or concerns about the blindfolding process or any other aspect of the study, please do not hesitate to reach out to the study staff.