



Key Health



SHINGLES CLINICAL TRIAL

**Investigating a potential new treatment
for shingles pain.**

What is the purpose of the study?



The investigational product, Solexan™, has already been registered by the FDA (Food and Drug Administration) as a topical antifungal, and researchers have gathered early-stage evidence that Solexan™ may stop the shingles virus from multiplying. Solexan™ is a topical white foam that can be applied directly to shingles lesions for 10 consecutive days, morning and night. The purpose of this study is to evaluate the safety and tolerability of this product, its ability to reduce the pain associated with shingles lesions, and to gauge the healing response of the lesions.



Shingles is a viral infection that occurs when the varicella-zoster virus, the same virus responsible for chickenpox, is reactivated and travels along nerve pathways to cause shingles lesions - painful, fluid-filled blisters that typically appear in a band- or strip-like pattern on one side of the face or body.

What is Shingles?



The pain associated with shingles lesions is often described as a burning, throbbing, or stabbing sensation, and it can persist for weeks if not months after the lesions have healed.

Why is this study important?

Though oral antiviral drugs can be used to treat shingles, they must be taken within 72 hours of symptoms starting - otherwise, they won't work as well, and many doctors won't prescribe them. However, meeting this 72-hour limit can be difficult, as people might not seek medical care when their symptoms first emerge, and many doctors cannot schedule appointments with such short notice. Further to this, oral antivirals only have a modest effect at reducing shingles pain. As such, many shingles patients don't get the best available treatment. Participating in this research study will provide investigators with valuable information about whether Solexan™ is a safe and effective treatment for shingles pain.



Who is sponsoring this study?

This study is being sponsored by Wintermute Biomedical, a pharmaceutical company located in Melbourne, Australia and Missoula, Montana. Wintermute spent the first ten years of their medical research journey looking for solutions to drug resistant infections, and subsequently discovered a way to unlock the natural germ-fighting abilities of fatty acids found in everyday foods. Wintermute collaborates with the likes of Johns Hopkins Medicine, Public Health England, and the University of Melbourne, and work tirelessly to ensure their solutions meet the goals of performance to address unmet needs and safety for human health and the environment.



**Wintermute
Biomedical**



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Who can participate?

To take part in this study, you will need to meet all the following:

- You are aged 18 or over.
- You have been diagnosed with shingles and have at least three distinct visible lesions on your torso, trunk, arms, or legs.
- You started experiencing shingles symptoms (lesions/rash) within three days of starting the study.



Who cannot participate?

Unfortunately, if any of the following apply to you, this study is not the right fit for you:

- You have any *significant infection diagnosis other than shingles.
- You are taking any medication or drugs that could impact how your body experiences pain (these will be discussed during screening).
- You have birthmarks, tattoos, wounds, or other skin blemishes or conditions at the planned treatment site (where the shingles lesions are located) - these will be assessed on a case by case basis.

*Please note, additional eligibility criteria apply and will be discussed during the screening visit.

What is involved?

If you are deemed eligible for the study, your participation is expected to last up to 31 days, and you will be required to attend the study site a minimum of 5 times. This includes:

- A site screening visit, which will take about 2 hours.
- A randomisation and treatment period of 10 days, which includes site visits on Days 1, 5 and 11.
- A follow-up site visit on Day 30.
- Maintain a patient diary over the course of the clinical trial.

This is a double-blinded study, which means neither you nor the study doctor will know if you receive the investigational product or a placebo. A placebo looks like the study medicine but does not contain any study medicine (active ingredient). Researchers use a placebo to see if a study medicine is safer than not taking anything at all. Eligible participants will have a two in three chance of receiving the investigational medication.

Participation in this research is voluntary, and you may withdraw from the study at any time. By participating in this research study, you could potentially help advance medical breakthroughs in the treatment of shingles pain.

FOR MORE INFORMATION and TO REGISTER YOUR INTEREST, please speak with your doctor today as this study is only applicable to those who present shingles symptoms within three days of study commencement.

Visit www.keyhealth.com.au/trials or scan the QR code.

This trial has been approved by an independent ethics committee.

