Study to Evaluate the Safety and Pharmacokinetics of Topically Applied 40% Lidocaine Gel Compared with Placebo in Subjects With Acute Herpes Zoster (Shingles) Pain

ACTRN12615000033549

Status	RECRUITING
Sponsor	Centrexion Corporation
Enrollment	16 participants

Plain Language Summary

This study is testing a high-strength lidocaine gel (40%) applied to the skin to relieve pain from shingles (herpes zoster). Shingles causes a painful rash and can lead to severe nerve pain. The gel is applied directly to the area where you feel the allodynia — a type of pain where even light touch, like brushing clothing against the skin, is very painful. Participants are randomly assigned to use either the lidocaine gel or a placebo gel and researchers track how their pain changes.

You may be eligible if:
- You are between 18 and 85 years old
- You have been diagnosed with shingles (herpes zoster)
- Your rash appeared within the last 20 days
- Your rash is on your trunk or limbs (not face, head, neck, or genital area) and covers less than 300 cm2
- Your pain score is 4 or above out of 10

You may NOT be eligible if:
- Your shingles rash is on your face, head, neck, or genital/rectal areas
- You are allergic to lidocaine or local anaesthetics
- The rash area is broken, inflamed, or not intact
- You take Class I antiarrhythmic heart medications

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (6)

- Subject is a male or female > or = 18 years of age and < or = 85 years of age.
- Subject has brush-evoked allodynic pain intensity score > or = 4 using the NPRS as determined by pain assessment during the physical examination at screening.
- a. Onset must have occurred < or = 20 days prior to randomization
- Subject has an average daily pain intensity score of > or = 4 using the NPRS as determined by pain assessment during the physical examination at screening.
- Subject must have a diagnosis of herpes zoster (shingles).

... and 1 more (see full listing online)

Exclusion (6)

- Subject has an active herpes zoster lesion on the face, head, neck, genital or rectal areas.
- Subject has rash limited to trunk and limbs, with a total surface area greater than 300 cm2.
- Subject has a known history of allergic reaction, hypersensitivity, or clinically significant intolerance to lidocaine, ingredients of the study drug, or local anesthetics of the amide type.

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12615000033549

• Subject has target skin area (allodynic area and surrounding skin) that is not intact, is inflamed, or in the opinion of the Principal Investigator, consistent with rash due to acute herpes zoster.

• Subject has any other form of pain that was not discernible from herpes zoster (shingles) allodynia.

... and 1 more (see full listing online)

Locations (1 total)

VIC, Australia