

Study of the Safety of PM Shingles Rescue to Treat Symptoms of Postherpetic Neuralgia: a randomized, double-blinded, placebo-controlled, cross-over trial

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Abstract:

Background: Postherpetic Neuralgia (PHN) is defined by lingering nerve pain that results from a Herpes Zoster outbreak. The currently available treatments for this painful and disabling condition are not always sufficient.

Methods: Subjects were chosen to receive both the test and the placebo, but in random orders in a cross-over method with washout periods in between treatment phases. Subjects rated their symptoms on a daily basis.

Results: One subject reported increased pain during the treatment week of the trial.

Conclusions: The results suggest that the treatment is as safe as a placebo.

Background:

Herpes Zoster (shingles) is a virus that affects nearly 800,000 people annually in the United States alone. Once the sores are gone, usually after 8 to 10 weeks, nearly half of shingles sufferers experience the lingering discomfort of postherpetic neuralgia (1). The pain and nerve inflammation of postherpetic neuralgia can last from months to years (2).

Clinical studies on Famvir (famciclovir) have suggested that 44% of those who endure shingles will go on to experience postherpetic neuralgia (1). For those who received treatment with Famvir within 72 hours of shingles onset, the median time of the PHN was 63 days. Those who received no treatment had a median duration of PHN of 119 days. Unfortunately, there are some cases of PHN that can continue for years (1).

The standard of medical care for PHN is pain relievers (3, 4, 5). Recommended pain relievers can be taken orally, such as Darvoset, or can be applied in time-release patches directly to the painful area, such as a lidocaine patch (Lidoderm) (6). Long-term use of painkillers has been found to be physiologically problematic from a number of perspectives. Alleviating the pain and discomfort associated with PHN has presented clinicians with a difficult task. This difficulty is evident in the wide range of drugs prescribed, which includes, but is not limited to, anti-virals, anticonvulsants, antidepressants, local anesthetics, opiates, and nerve blocks (2). Since the lesions are usually healed within 10 weeks and the PHN can last from months to years, the majority of suffering occurs in the PHN stage of the condition (1). A product that could soothe the neural inflammation and reduce suffering during the prolonged period of PHN would be a tremendous benefit to sufferers of Herpes Zoster.

This is a protocol for testing the safety of Peaceful Mountain Shingles Rescue, an herbal gel that is administered topically. This gel contains herbal agents with antiviral, anti-inflammatory, and tissue regenerating properties. This product has demonstrated the ability to terminate the active stage of shingles and extinguish the pain and neuralgia associated with the lingering effects in initial testing. It has even been shown to even diminish the pain of PHN as well as Lidoderm patches, in patients who have been suffering for more than 10 years.

Methods:

Subjects were recruited from local advertisements such as flyers and newspapers and study visits were held at the Klearsen Corporation clinical research department. Subjects were required to have a history of physician diagnosed shingles, to be currently experiencing symptoms of postherpetic neuralgia in any

region, and to be at least 18 years of age. Subjects were only allowed to use medications that they had already been using consistently and were required to maintain the dose during the trial period.

Following a comprehensive screening questionnaire and upon consented enrollment, subjects were randomly assigned to the order in which they would receive the test and the placebo. Subjects were required to attend weekly visits at the clinic to complete weekly side effect surveys and to have the gel tub weight assessed. At the first clinic visit, each subject completed a symptom survey and was instructed complete daily surveys for the duration of the trial. During the first week of the trial, the subject did not apply any gel, this is referred to as the Baseline Phase. The First Treatment Phase began following the second visit where the subjects were given the gel tub that had been randomly assigned to them. They were instructed to liberally apply the gel to the affected region 3 times daily. At the third visit, the subjects were instructed to discontinue the first treatment and to only complete daily surveys during the upcoming, Washout Phase, week. At the fourth visit, the subjects were given a tub of the second treatment, which was different from the first and directed on its use, thus beginning the Second Treatment Phase. At the fifth visit, the subjects were instructed to discontinue the use of the gel and to continue completing daily surveys for the last week, the Return to Baseline Phase, of the study. At the sixth and final visit, the subjects completed a final weekly side effect survey and were informed of the order in which they were given the test and the placebo.

Results:

Variable	Placebo/Test (n=7)	Test/Placebo (n=5)
Age in years	65.5 (15.0)	67.5 (14.9)
Time since last shingles outbreak in months	15.0 (17.1)	27.6 (39.1)
Time for sores to heal from last out break in months	0.85 (0.50)	0.67 (0.30)
No. of women (%)	3 (43)	3 (60)

Table 1 Baseline characteristics for both groups. Placebo/Test indicates that the group received a placebo first and then the test gel whereas the Test/Placebo group received the test product first and the placebo second. Values are averages (±standard deviation) unless otherwise stated.

Only one subject experienced a side effect during the trial. During the treatment week one test subject reported an increase in pain where the treatment was being applied. No side effects were reported during the placebo week.

Discussion:

An increase in pain could be caused from a subject rubbing the area frequently or the natural progression of the condition. The side effect did not last beyond the treatment week. These results suggest that the treatment is as safe as a placebo gel when used for at least one week. This treatment could be beneficial for people with painful PHN and should be investigated in further testing.

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