

Study of the Safety of Peaceful Mountain Sinus Rescue to Treat Chronic and Acute Sinusitis: a randomized, double-blinded, placebo-controlled trial

Breeana K. Saffell, Steven R. Frank, Mark J. McNamara, Rosia Warner, and Gary B. Clark, MD

Abstract:

Background: Due to the increased occurrence of sinus infections, the use of antibiotics is also increasing, thus leading to potential antibiotic resistance. An alternative treatment for sinusitis is widely needed and should be evaluated. The investigational agent tested in this trial is Peaceful Mountain Sinus Rescue (PMSR), a silver based product.

Methods: Subjects suffering from either chronic or episodic sinusitis were randomly selected to treat their symptoms with either a test or a placebo nasal spray. Subjects rated their daily symptoms on scales ranging from 1 to 9 in order to assess improvement. The treatment was initiated on the first day of the trial and continued for three weeks.

Results: Both groups reported side effects with 69% of the placebo group and 57% of the test group reporting side effects some time during the treatment phase.

Conclusions: The side effects were minor and most of the side effects were symptoms of the condition including headache, sore throat, and sneezing. With both group experiencing minor side effects the results suggest that Peaceful Mountain Sinus Rescue is as safe as a placebo during 3 weeks of treatment.

Background:

Sinus infections affect more than 30 million people annually in the United States alone¹. Most sinusitis sufferers have numerous infections per year resulting in very regular antibiotic use. This regular antibiotic use often leads to an escalation in the potency and cost of the prescribed drugs. Prolonged use of antibiotics can also lead to a number of serious side effects including gastrointestinal disturbances, myalgias, and systemic allergic reactions². A number of patients who remain unresponsive to other medical interventions resort to reconstructive surgery or surgical removal of nasal polyps, but many patients experience polyp regrowth¹.

These therapies may not be treating the cause of chronic sinusitis. It is thought that an allergic response to fungi could be a cause³. One study found that 100% of the chronic sinusitis subjects being tested had fungus in their mucus⁶. If this is the case, an antifungal treatment would be beneficial.

The product being tested, Peaceful Mountain Sinus Rescue (PMSR) is administered intra-nasally from a spray bottle according to a protocol and in a concentration covered by U.S. Patent # 6,454,754. The solution is an aqueous colloid of silver. This solution has shown anti-bacterial and anti-fungal properties in laboratory testing and could potentially be a safe sinusitis treatment.

Methods:

Subjects were required to have a history of recurring sinus infections, to be currently presenting symptoms, and to be at least 18 years of age. Subjects were disqualified if any antibiotics were used within 2 months prior to beginning the trial, or if any other remedies were used during the trial period. Following a comprehensive screening questionnaire and upon consented enrollment, subjects were randomly assigned to receive a bottle of placebo or test solution to begin using on their first day of the trial. At the first clinic visit, each subject completed a side effect survey and was instructed to apply the nasal spray with one spray in each nostril every 30 minutes throughout the day for the next 21 days. In addition, the subjects were sent home with side effect surveys to complete daily. The subjects were required to attend weekly visits at the clinic. These weekly visits consisted of a verbal interview, the completion of a weekly side effect survey,

and the weighing of the spray bottle that was assigned to them. At the final visit (visit 4), subjects completed a final weekly side effect survey, returned their spray bottle, and completed a verbal interview.

Variable	Test (n=15)	Placebo (n=13)
Age	42.5 (\pm 13.2)	48.5 (\pm 16.1)
No. women (%)	6 (40)	10 (77)
Duration of the condition in years (range)	12.9 (3-40)	20 (16.3)
Frequency of infection per year	5.2 (\pm 2.9)	5.8 (\pm 4.0)
Average length of each infection in weeks	4.6 (\pm 5.7)	2.3 (\pm 1.5)
No. chronic subjects (%)	9 (60)	5 (38)

Table 1 Baseline characteristics for the test and placebo groups. Values are averages (\pm standard deviation) unless otherwise stated.

Results:

Minor side effects were experienced in both groups. For the overall study approximately 69% of placebo subjects and 57% of test subjects experienced some type of side effect during the treatment phase of the trial (Fig 1).

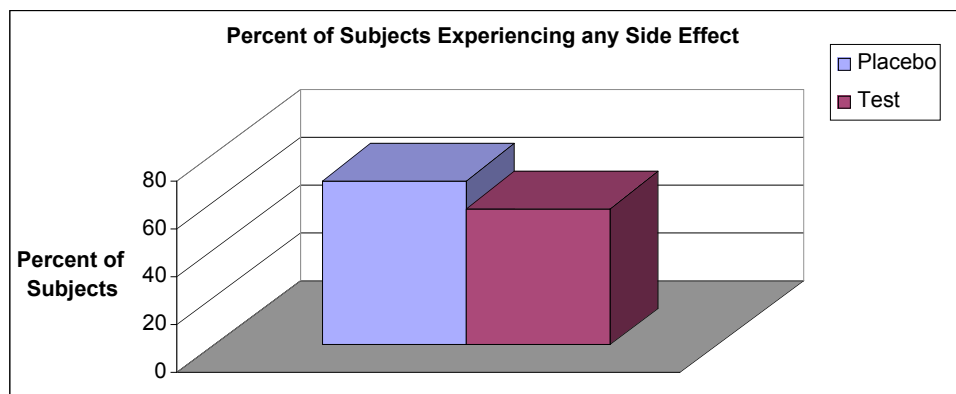


Fig 1 The percent of subjects that experienced some type of side effect during the three-week treatment phase of the study in the placebo and test groups.

The most common side effect in the placebo group was headache and nasal irritation with 31% of the subjects experiencing these side effects. The placebo subjects also reported sore throat, sneezing, and a decreased ability to taste. The test group reported nasal irritation as the most common side effect, with 29% of the group experiencing this effect sometime during the trial. Other side effects the test group reported were sore throat, headache, and a bad taste in the mouth. Figure 2 displays all the side effects that were experienced by both groups during the trial.

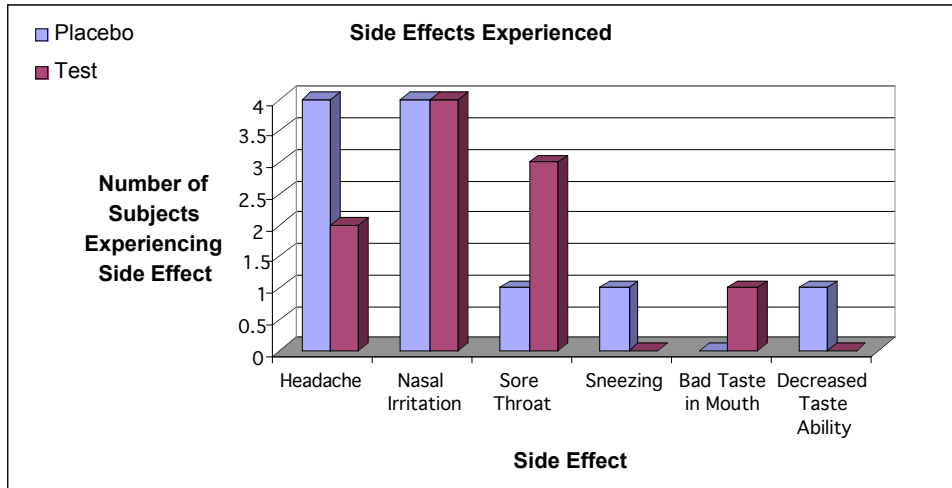


Fig 2 The number of people that experienced a certain type of side effect during the 3 week treatment phase of the study.

Not all side effects lasted the duration of the trial. Side effects were noted each week of treatment. The percentage of subjects experiencing a side effect was calculated and graphed in Figure 3.

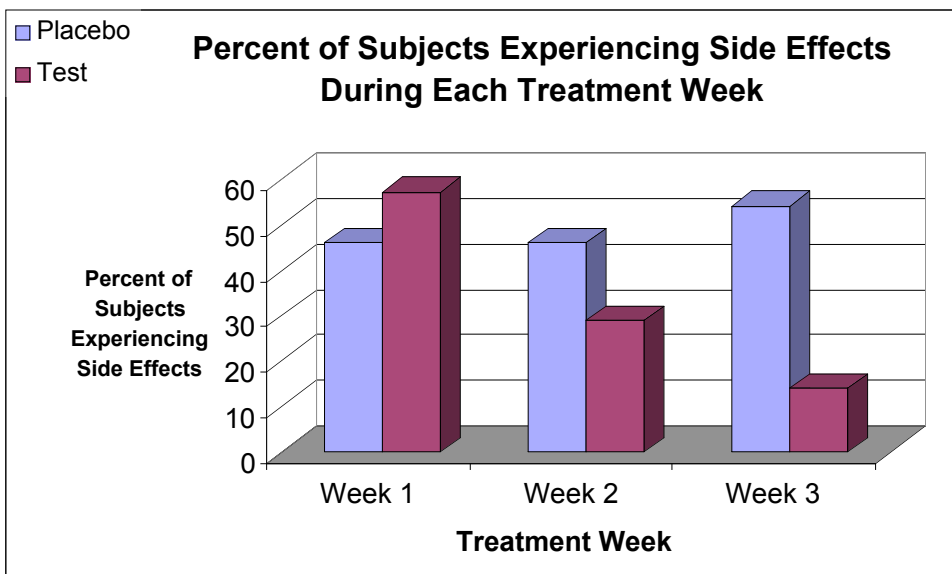


Fig 3 When the subjects reported the side effect they experienced.

The test group experienced most of the side effects during week 1. The number of side effects decreased with each week of treatment. The placebo group experienced about the same number of side effects during each week of treatment.

Discussion:

Minor side effects were experienced in both groups during the treatment phase of the study. The most common side effect in both groups was nasal irritation. Both groups also experienced headache, and sore throat. The placebo group experienced increased sneezing and a decreased ability to taste. The test group had one subject experience a bad taste when using Peaceful Mountain Sinus Rescue. Most of these side effects, including headache, sore throat, and sneezing, are symptoms of a sinus infection and can be hard to distinguish as a side effect or just the progression of the condition. None of these side effects were permanent or harmful to the subjects. The fact that both groups experienced similar side effects suggest that Peaceful Mountain Sinus Rescue is as safe as a placebo spray for 3 weeks of treatment. It would be

beneficial to test Peaceful Mountain Sinus Rescue against common treatments for sinusitis including antibiotics and other nasal spray products to compare severity of side effects.

References:

1. Kaliner, Michael (1998). Medical management of sinusitis. The American Journal of the Medical Sciences, 316(1), 21-8.
2. Vaughan, Winston C., Carvalho, Gerard (2002). Use of nebulized antibiotics for acute infections in chronic sinusitis. Otolaryngol Head and Neck Surgery, 127, 558-68.
3. Desrosiers, Martin Y., & Salas-Prato, Milagros (2001). Treatment of chronic rhinosinusitis refractory to other treatments with topical antibiotic therapy delivered by means of a large-particle nebulizer: results of a controlled trial. Otolaryngol Head Neck Surg, 125, 265-9.
4. Borges Dinis, Paulo, Conceicao Monteiro, Maria, Luz Martins, Maria, Silva, Nuno, Gomes, Augusto (2000). Sinus tissue pharmacokinetics after oral administration of amoxicillin/clavulanic acid. Laryngoscope, 110(6), 1050-5.
5. Ponikau J, Sherris D, Kern E, et al. The diagnosis and incidence of allergic fungal sinusitis. Mayo Clin Proc 1999; 74:877-884.
6. Taylor M, Ponikau J, Sherris D, Kern E, Gaffey T, Kephart G, Kita H. Detection of fungal organisms in eosinophilic mucin using a fluorescein-labeled chitin-specific binding protein. Otolaryngol Head Neck Surg. 2002;127:377-387.
7. Brook, Itzhak (2002). Bacteriology of acute and chronic sphenoid sinusitis. Ann Otol Rhinol Laryngol, 111, 1002-4.
8. Chan, Kenny H., Winslow, Catherine P., Levin, Myron J., Abzug, Mark J., Shira, James E., Liu, Andrew H., Simoes, Eric A., Strain, John D., & Stool, Sylvan E. (1999). Clinical practice guidelines for the management of chronic sinusitis in children. Otolaryngol Head Neck Surg, 120, 328-34.
9. Don, Debra M., Yellon, Robert F., Casselbrant, Margaretha L., Bluestone, Charles D. (2001). Arch Otolaryngol Head Neck Surg, 127, 1093-8.
10. Lavigne, Francois, Cameron, Lisa, Renzi, Paolo M., Planet, Jean F., Christodoulopoulos, Pota, Lamkioued, & Bouchaib, Hamid, qutayba (2002). Intranasal administration of topical budesonide to allergic patients with chronic rhinosinusitis following surgery. Laryngoscope, 112(5), 858-864.
- Legent, F., Bordure, Ph., Beauvillain, C., & Berche, P. (1994). A double-blind comparison of ciprofloxacin and amoxicillin/clavulanic acid in the treatment of chronic sinusitis. Chemotherapy, 40(suppl 1), 8-15.
11. Leonard, David M., & Bolger, William E. (1999). Topical antibiotic therapy for recalcitrant sinusitis. Laryngoscope, 109(4), 668-70.
12. Ramadan, Hassan H., Hathers, Peter H., & Schwartzbauer, Heather (2002). Role of anaerobes in chronic sinusitis: will polymerase chain reaction solve the debate. Otolaryngol Head Neck Surg, 127, 384-6.
13. Wald, Ellen R. (1998). Microbiology of acute and chronic sinusitis in children and adults. The American Journal of the Medical Sciences, 316(1), 13-20.
14. Wallwork, Ben, Coman, William, Fernon, Francois, Mackay-Sim, Alan, & Cervin, Anders (2002). Clarithromycin and prednisolone inhibit cytokine production in chronic rhinosinusitis. Laryngoscope, 112(10), 1827-30.

15. Willard, Craig C., Eusterman, Vincent D., & Massengil, Philip L. (2003). Allergic fungal sinusitis: report of 3 cases and review of the literature. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology & Endontics, 96(5), 550-60.