Efficacy Study Compounded Innocan Pharma's Topical Pain Relief Spray* for Treating Pain Symptoms

Study Description

Brief Summary:

The main objective of this protocol is to determine the effectiveness of using compounded topical pain Spray for treating chronic pain and pain associated with a specific event.

The secondary objective is to determine the relative satisfaction with the Spray. The investigators hypothesis is that the active pain spray may provide significant benefit.

Specific Aims

1. Specific Aim 1 will determine pain relief following treatment with the appropriate (based on specified pain) compounded topical pain Spray. The investigators hypothesis is that the compounded topical pain spray will provide pain relief.
2. Specific Aim 2 will measure the patient satisfaction with the spray. The investigators hypothesis is that the compounded topical pain spray will improve patient satisfaction, with their pain treatment.

Study Design

Study Type: Interventional (Clinical Trial)

Actual Enrollment: 18 participants

Allocation: Randomized

Intervention Model: Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: Randomized, Controlled, Double-blind, Efficacy Study Compounded Topical Pain Spray

Actual Study Start Date: September 9, 2020

Actual Primary Completion Date: September 9, 2020

Actual Study Completion Date: October 15, 2020

Eligibility Criteria

1. Age > 18; -90
2. A localized pain complaint to include back, arthritis, neurogenic, postsurgical, post-trauma
3. Average pain score ≥ 2/5 over the past week.
4. Pain duration > 4 weeks

Contacts and Locations

Sponsors and Collaborators: Center for Podiatric Care & Sports Medicine, NYC, NY

Principal Investigator: Dr. Josef Geldwert, DPM, FACFAS – Board Certified Podiatrist/Podiatric

Physician & Surgeon

Abstract

This study aimed to test Pain Relief spray based on Cannabidiol and Magnesium. Eighteen participants (8 Male and 10 Female) with different ages (Average age 50) were tested for this intention. Most participants described their pain as throbbing and uncomfortable and a few distressing. The location of the pain varied from the upper extremity to the back to the lower extremity and feet. 80% of the participants were on some type of medication either prescribed or OTC and many were on physical therapy to deal with their pain. Ten of them were with chronic pain and eight associated eight specific events. The data shown around 83.3% of participants noticed an immediate improvement in pain relief after 20 minutes with 44 % of the participants reporting a relief greater or equal to 50%. The participants showed even much more improvement after 60 minutes where almost all of them shown impressive result. After 24 hours no significant change was observed. It is worth noting that the results are based on the self-assessment of the volunteers. It is also worth noting that there were no side effects

Introduction

Pain is described by the International Association for the Study of Pain as a multidimensional entity including nociception, central nervous system afferents, regulation, affective responses, endogenous analgesia, behavioural modifications, and social life function. Pain degenerates to an individual response when pain cause factors are experienced, manifesting even though the main stimulus can be eradicated. Chronic pain tends to defy health providers, despite scientific advancements and thoroughly developed therapies, since it is a poorly controlled disease, partially because there are three dimensions involved in pain pathogenesis: nociception (pain sense and topography), mental (fear and depression), and physiological causes (catastrophism, caution, and somatic consciousness). Due to core effects, pain treatment faces obstacles that limit clinical efficacy, such as the limited potency of analgesics, structural effects, and cognitive disability of medications. When the understanding of pain pathophysiology and management grows, to aim to block pain at peripheral locations, with maximal active opioid and reduced systemic effects, novel routes of opioid transmission are being discovered. The product of such experimentation is topical preparations.

In terms of side effects, research-based on scientific practice has suggested that topically administered drugs can be almost as effective as those given orally, with a strong safety profile. Improving patient commitment to medical care by delivering adequate pain relief with fewer central nervous system effects and reduced opioid regimen pressure is the ultimate aim that motivates the production of topical preparations. Increasing emphasis has been put on designing alternative routes of drug delivery to provide patients with personalized therapies, without diminishing the potency of analgesia, in proportion to the development of pain mechanism information. Although acute pain is a warning, persistent pain is a condition that involves a meticulous collection of high bioavailability analgesic medications for long-term usage. These requirements are barriers that topical drugs strive to resolve, enabling the active ingredient to be administered gradually, retaining steady plasma levels, with a strong safety profile. To this aim, we intend to test and later on to patented the **Pain Relief Spray based on** Cannabidiol and Magnesium

Material and methods

Eighteen participants (8 Male and 10 Female) with different ages (Average age 50) were selected to be tested with the spray for pain relief (Table 1). All of them were previously diagnosed with one or several chronic pain (Table 2). All measured variables and derived parameters were tabulated by descriptive statistics. For categorical variables, summary tables were provided giving sample size, absolute and relative frequency. For continuous variables summary tables were provided giving sample size, arithmetic mean, standard deviation, coefficient of variation (CV%), median, minimum and maximum and 95% CI (Confidence Interval) for means of variables. The data were analyzed using the SAS ® version 9.4 (SAS Institute, Cary North Carolina).

Table 1: Demographics (Part 1 of 2)

	N	Mean	Std	CV (%)	Min	Median	Max
Age	18	50.28	10.59	21.07	35.00	50.00	73.00

Table 1: Demographics (Part 2 of 2)

	N	%
Gender		
Male	8	44.44
Female	10	55.56

Table 2: Pain before application description

	N	Yes %	No%
Type of pain = Chronic	18	61.11	38.89
Type of pain = Event	18	44.44	55.56
Chronic = Arthritis	18	16.67	83.33
Chronic = Lower Back	19	33.33	66.67
Chronic = Neurogenic pain	18	16.67	83.33
Chronic = Possurgical pain	18	16.67	83.33
Chronic = Post-trauma pain	18	16.67	83.33
Event = Sports	18	11.11	88.89
Event =Excercise/Working Out	18	38.89	61.11
Pain feeling = Flickering	18	11.11	88.89
Pain feeling = Pulsating	18	11.11	88.89
Pain feeling = Throbbing	18	66.67	33.33
Pain feeling = Beating	18	0	100.00
Pain feeling = Pounding	18	5.56	94.44
Pain description = Mild	18	11.11	88.89
Pain description = Uncomfortable	18	72.22	27.78
Pain description = Distressing	18	22.22	77.78
Pain description = Extreme	18	5.56	94.44
Pain description = Excruciating	18	0	100.00
Pain Site = Upper back	18	11.11	88.89
Pain Site = Lower back	18	27.78	72.22
Pain Site = Neck	18	16.67	83.33
Pain Site = Joints	18	5.56	94.44
Pain Site = Muscles	18	16.67	83.33
Pain Site = Legs	18	16.67	83.33
Pain Site = Feet	18	27.78	72.22
Pain Site = Other	18	44.44	55.56

Result and Discussion

From figure 1, we can observe that around 83.3 % of participants noticed an immediate improvement in pain relief after 20 minutes with 45% of the participants reporting greater than a 50% improvement. As somehow it was expected, after 60 minutes of application, 95% of participants noted relief from pain with over 60% relating greater than 50% relief. Some reported as much as 90% relief from pain. It should be noted that after 24 hours no significant change was observed when is compared with 60 minutes' application associated to improvements where almost 90% of participants have shown a pain relief with almost 40% relating greater than 50% relief. Considering all the above mentioned, the spray for pain relief tested to these participants show considerable effect even one hour after application. Suggesting the power of pain relief of spray due to synergistic effects of all active ingredients, Cannabidiol and Magnesium

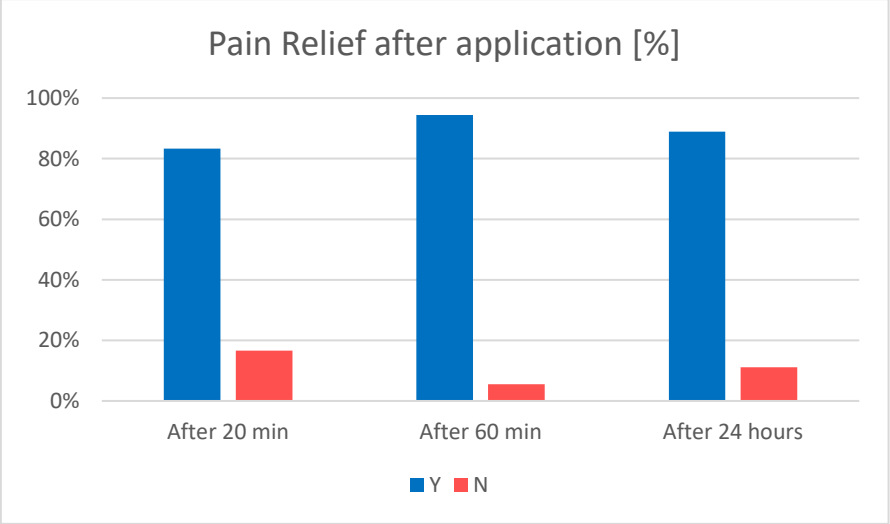

Figure 1. Pain relief after application by categorization (all subjects)

Regarding satisfaction score, figure 2 displays the result of participants. All participants have shown improvement on the satisfactory score associated with the pain relief. More in detail, related to sleep performance, around 50% of participants exhibited a score equal or greater than five and the rest less than five. Similarly, all participants related to their muscles relaxation felt more relaxed with over 50% score over 50% improvement. In short, a satisfactory score on relaxation derived the same data as in case of sleep performance previously explained. Another important issue is that all participants were satisfied with the product with over 60% giving the Relief and Go Spray a rating of 7/10 or greater.

Figure 2. Satisfaction scores by categorization (all subject)

The resulting pain relief after application by categorization “event pain” are more exact, there several distinctions between pain relief ‘event pain’ and “all subject” (Figure 1). Application time didn’t play a specific effect on “event pain”. Conversely, form the data obtained in figure 1, application time on 'all subjects' is an important factor which cannot be neglected. Also, Score of pain relief in 'all subjects' it varies from 20 min application to 24 hours. Unlikely from the data on figure 2, score pain relief 'event pain' remained unchanged to various application time. It is noteworthy that, on 'event pain' all participant noticed remarkable improvement-based spray relief pain application. Another important issue on ‘event pain’, is the satisfactory score result. More specifically, sleep performance and muscle relaxation form all participant obtained, gave similar response with over 70 % of participants presented a score performance less than five and 30 % of participants displayed score performance equal or above five. The overall satisfaction after using the spray provided data such as over 85 % of participant produced a score performance over five and the rest (15%) less than five.

Pain relief 20 minutes after application distribution (all population) is represented the distribution of pain relief after 20 minutes of application. In sum, around ten participants relieved pain less than 50% in 20 minutes and 7/18 of the participants reporting a relief greater or equal to 50%. Noteworthy, 1/18 participant is shown to relieve pain at around 90 % which in turn, is an impressive result.

As it was explained earlier, the performance was further improved when the application time was enhanced. After 60 minutes over 60 % of participant reported a relief greater than 50%. In contrast, after 24 hours'

application, the results show that over 70 % reported pain relief of less than 50 %. On the other words, application for 60 minutes is sufficient enough to obtain remarkable results.

Five participants exhibit a sleep performance score 1, one of participant performance score 2 and around 3 participants performance score on sleeping 4. The rest of the participant displays a performance score above five. A different situation is obtained from the muscle relaxation where for around nine participants are reported a score between 4-6. Moreover, four participants report a score 8 and 9. Going one step further, nine participants have a satisfactory score 8 and 9. Additionally, the other four of eighteen report a score from 5 to 7. To date, over 70 % of the participant's scores equal to or higher than five.

here is no doubt of effect regarding pain relief after spray application on "event pain". After 20 min of application, over 28% of participant relieve pain less than 20 %. Thereafter, we have an enhanced pain relief score for the rest of participants. In detail, we have around 14 % of participants with a score of 30%, 50%, 70%, 90% respectively. Specifically, 14 % of participant's reports less than 20 % pain relief, again other 14 % of participants with 30 % relief and so on. To be more exact, over 55 % of participants reported a pain relief more than 55 %, the rest, shown a relief less than 50 %. To this end, participants would recommend the Relief & Go pain spray related to impressive data obtained.

It has been frequently witnessed, that satisfaction score is in acceptable agreement with the explanation in the previous section of this study. In general, for all three aspects (Sleep, muscle relaxation and overall satisfaction most of the participant reported data with satisfaction score above 5 and only a few of them less than five. Notably, in overall satisfaction and muscle relaxation, more 85 % of the participant has shown a score equal or over five which represent striking results for the future perspective of the spray for mass population application

Summary & Conclusions

This short experiment and research aimed to evaluate the performance of spray for pain relief integrating Cannabidiol and Magnesium ingredients. The random population were selected for the experiment. In more detail, eighteen participants (8 Male and 10 Female) with different ages (Average age 50) were tested with the spray for pain relief. All of them were previously diagnosed with one or several chronic pain to check the results after application. Different time application evaluated, and results gathered showed immediate improvement on participants on both categories "all population" and "event pain". Moreover, a score performance on three subjects (sleep, relaxation, satisfactory) was assessed and for all participant, the score was at least 1 with most of them reporting equal or higher than five score performance. Considering all the above mention, the spray offers a new alternative for pain relief based on data provided from the participants. To this end, further application on mass population would be recommended as around 85 % of participant reported positive feedback

*Innocan Pharma's Relief & Go OTC Pain Relief Spray

90mL / 3FL OZ, 250mg CBD isolate – 0% THC

Patent Pending Unique Formulation solution to relieve pain by combining three different mechanisms in one: (I) Menthol & Methyl Salicylate a topical analgesic, (ii) Magnesium a muscle relaxant, (iii) CBD an Anti-inflammatory – Together **over then 40% in the formula**.

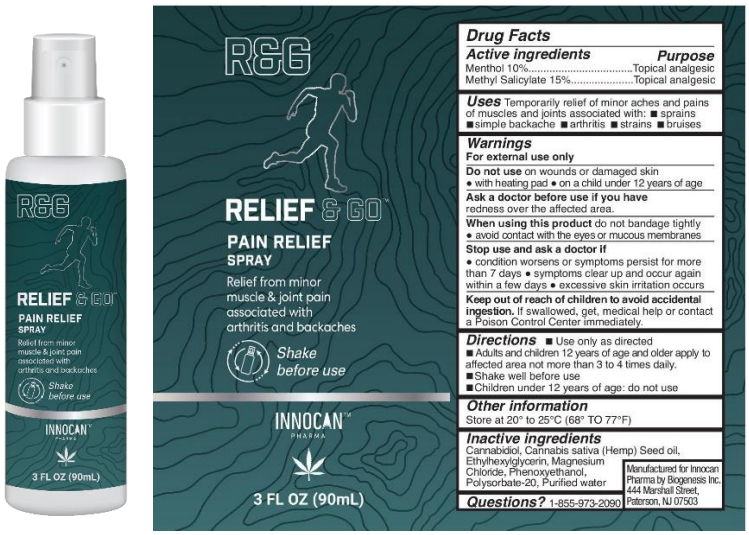

Figure 3. Innocan Pharma's OTC Pain Relief Spray - image and label

Ingredients and Benefits

Menthol can function as a topical analgesic (pain reliever) in certain skin care products. It absorbs into the skin producing a numbing effect. Menthol also causes blood vessels to widen, which increases blood flow in the area. This sends extra nutrients and can help with cellular repair.[1]

Methyl salicylate relieve musculoskeletal pain in the muscles, joints, and tendons by causing irritation and reddening of the skin due to dilated capillaries and increased blood flow. methyl salicylate is applied topically as counter irritant for relief of acute pain associated with lumbago, sciatica and rheumatic conditions. [2]

CBD is a potent antioxidant with anti-inflammatory and analgesic properties. CBD may also improve the skin's defense mechanism and its ability to regenerate. CBD could play a role in chronic pain management. The topical application of cannabinoids allows them to be absorbed directly into the affected area for faster and more focused relief.[3]

Magnesium is absorbed through the skin and is claimed to have health benefits, such as to relieve muscle pains and aches and to enhance relaxation. Many athletes swear by magnesium for post workout recovery. Studies indicate that magnesium spray may help reduce muscle cramping and replenish magnesium levels lost through sweat.[4,5]

1. Cannabinoid Delivery Systems for Pain and Inflammation Treatment, Molecules. 2018 Oct; 23(10): 2478.

2.Camphor induces cold and warm sensations with increases in skin and muscle blood flow in human, PMID: 25451841 DOI: 10.1248/bpb.b14-00442

3. The role and mechanism of action of menthol in topical analgesic products, PMID: 29524352 DOI: 10.1111/jcpt.12679

4. Permeation of topically applied Magnesium ions through human skin is facilitated by hair follicles, PMID: 27624531 DOI: 10.1684/mrh.2016.0402 https://bengreenfieldfitness.com/article/why-i-slather-my-body-with-magnesium-oil-after-every-hardworkout/

5. Efficacy and safety profile of a topical methyl salicylate and menthol patch in adult patients with mild to moderate muscle strain: a randomized, double-blind, parallelgroup, placebo-controlled, multicenter study, PMID: 20171409 DOI: 10.1016/j.clinthera.2010.01.016

About Innocan Pharma

Innocan Pharma is a pharmaceutical tech company that focuses on the development of several drug delivery platforms combining cannabidiol ("CBD") with other pharmaceutical ingredients as well as the development and sale of CBD-integrated pharmaceuticals. The Company's operations and research and development activities are based in Israel.

Innocan Pharma's business can be described as three distinct operating segments relating to the incorporation in products of CBD in their formulation: (i) the research and development of the treatment of Covid-19 (and other viruses causing lung inflammation as well as other central nervous system (CNS) diseases such as epilepsy and Alzheimer's Disease) by using CBD loaded exosomes ("CLX"); (ii) the research and development of the use of CBD loaded liposomes to provide pain relief and treat epilepsy and other central nervous system disorders and other indications; and (iii) the commercialization and sale of branded CBD integrated pharmaceutical and topical treatment products for relief of psoriasis symptoms as well as the treatment of muscle pain and rheumatic pain.

About the Author Nir Avram, CTO, MSc. Organic Chemistry

Nir Avram is a senior consultant in the areas of pharmaceuticals and cosmetics with over 30 years of experience. He consults in diverse areas of expertise including generic formulations and synthesis of novel materials, to start-ups as well as established companies. He is the VP of R&D at Emilia Cosmetics Israel and Emilia Resources in the US. Nir received an M.Sc. (Cum Laude) in organic chemistry from the Technion – Israel Institute of Technology, Haifa. He also holds several patents.

About Sponsor and Collaborator, The Center for Podiatric Care & Sports Medicine

The Center for Podiatric Care and Sports Medicine is dedicated to the diagnostic, therapeutic and surgical correction of foot and ankle disorders resulting from structural deformities and sports injuries. The Center's foot doctors specialize in: Bunion Treatment, Reconstructive Foot Surgery, Sports and Dance Medicine, Heel Pain Treatment, Computerized Gait and Pressure Analysis, Orthotics, Cryosurgery, Joint Replacement, Fracture Care, Arthroscopic & Laser Surgery -Pediatric Foot Care and Diabetic Foot Care.

About Principal Investigator Dr. Josef Geldwert, DPM, FACFAS

Dr. Josef Geldwert of the Center for Podiatric Care & Sports Medicine located in Manhattan has over 40 bars of experience in foot care with concentrations in reconstructive foot surgery, biomechanics, and sports injuries. The Center specializes in treating chronic problems resulting from sports injuries and active lifestyles. In addition to his extensive clinical and surgical training Dr. Geldwert has been a medical authority to numerous professional teams. Dr. Geldwert has served as the Co-Medical director of the NYC Triathlon, the Medical director of the Hamptons Marathon and a medical consultant to the NY Power professional Women's soccer team, the Women's Soccer World Cup, the US Olympic Marathon Trials, and Women's professional Tennis tournaments. These experiences coupled with his academic affiliations as a member of the Orthopedic faculty of the Mt Sinai Medical Center and Surgical Department of Mt Sinai Beth Israel, have made Dr. Geldwert a recognized expert in diagnosing and treating foot and ankle problems.

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