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Efficacy and safety of pain relief oil with 6% Cannabis extract in musculo-skeletal and joint pain disorders: A randomized, open-label, comparative clinical trial

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Abstract
Background: Acute musculoskeletal and joint injuries commonly cause pain, restricted movement, and functional disability, significantly affecting quality of life. While multiple treatment modalities exist, topical oil-based formulations provide a convenient, cost-effective option with rapid onset of action and minimal systemic adverse effects.
Method: This randomized, open-label, comparative clinical study included 30 participants with musculoskeletal and joint pain disorders, who were randomized to receive either Pain Relief Oil with 6% Cannabis Extract or Dr. Ortho Oil (n=15 each) and applied topically twice daily for two weeks. Efficacy of the test product was assessed using pain intensity scales, onset and duration of pain relief, functional outcomes, patient satisfaction, quality of life measures, and inflammatory markers, while safety was evaluated through monitoring adverse events.
Conclusion: Pain Relief Oil with 6% Cannabis Extract showed faster onset of action and better user acceptability with comparable efficacy to Dr. Ortho Oil in reducing musculoskeletal and joint pain. Both treatments reduced inflammatory markers, supporting Pain Relief Oil with 6% Cannabis Extract as an effective and convenient topical analgesic option.

Keywords: Pain relief oil, acute musculoskeletal, joint pain disorder

Introduction

Musculoskeletal disorders are a set of diverse conditions affecting bones, joints, muscles, and connective tissues [1]. These disorders are characterized by pain, discomfort, or functional impairment affecting the muscles, tendons, ligaments, nerves, joints, and supporting structures of the body [2]. Chronic pain and loss of function are the primary mechanism through which musculoskeletal disorders lead to disability and work loss [1]. MSD are said to be the reason for 40% of all chronic conditions, 54% of all long-term disability, 24% of restricted activity days and almost 20% of health care utilization [3].

The main purpose of the treatment is to relieve pain and ameliorate stiffness and other physical conditions. Pharmacological treatments of MSDs include topical or oral analgesics (non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, tramadol, and opioids), chondroitin sulphate, glucocorticoids, disease-modifying antirheumatic drugs (DMARDs) and other drugs. Painkillers may have serious side effects, especially in the case of long-term usage (in chronic disorders) and in the case of high doses [4]. Conventional management of MSD pain involves nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and physical therapy. However, systemic NSAIDs are associated with adverse effects, including gastrointestinal, renal, and cardiovascular complications. This has prompted a shift towards safer, localized treatments. Topical NSAIDs, including gels, creams, and sprays, offer localized pain relief with minimal systemic exposure, making them a safer alternative for many patients [5].

PAIN RELIEF OIL is a topical formulation designed to reduces acute and chronic pain & inflammation in low back pain, arthritis and sports injury. This study investigates its efficacy, safety, and tolerability in comparison with Dr Ortho Oil, aiming to provide a safer and effective option for pain management.

Methodology

Study Design and Study Centers

A Randomized, Open label, Comparative, clinical study to evaluate the efficacy and safety of Pain Relief Oil with 6% Cannabis Extract in Participants with musculoskeletal and joint pain disorders. The study was conducted at two sites in India: Thirumalai Medical Centre, Puducherry (No. 408, Cuddalore Road, Nainarmandapam, Puducherry–605004), and Oxymed Hospital Medical & Healthcare Center, Chennai (No. 14/1, 2nd Street, 3rd Main Road, Nandanam, Chennai–600035.

Ethical Approval and Trial Registration

The study protocol was approved by the Ethics Committee, Ethique De La Nature Association (registration no: ECR/376/Indt/PY/2023) & Oxymed Ethics Committee-Institutional Ethics Committee (registration no: ECR/1861/Inst/TN/2023) the trial was registered prospectively in the Clinical Trials Registry of India (CTRI) on August 24, 2024 (registration no: CTRI/2024/08/072905).

This study was conducted in compliance with the International Council for Harmonization-Good Clinical Practice (ICH-GCP) guidelines E6 (R2), 2016; the Indian

Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017; the Declaration of Helsinki, 2013; and all applicable local regulatory requirements and institutional policies. Written informed consent was obtained from each participant prior to study initiation.

Study Procedure and Treatment Randomization

After obtaining written informed consent, participants underwent a detailed screening procedure. Screening included participants demographic data (gender, height (cm), weight, (kg), Body Mass Index (kg/m2) and age in years), personal history, medical history (allergy) and the systemic examination. Efficacy and safety assessments were conducted on day 0, and day 7.

A total of 30 participants were enrolled and randomized into two parallel treatment arms, with 15 participants allocated to each group using a block randomization schedule.

T-Test (n=15): Pain Relief Oil with 6% Cannabis Extract

C-Comparator (n=15): Dr Ortho Oil

Both interventions were applied topically twice daily for a duration of 2 weeks, as directed by the Investigator.

Study Population

Men and women aged ≥18 years diagnosed with acute or chronic localized musculoskeletal pain and joint pain disorders, including arthritis, were enrolled in the study. Participants were eligible if they were able to understand written and/or verbal study instructions and were willing to comply with all study-related procedures. All participant provided written informed consent prior to initiation of study procedures.

Participants were good health, as determined by medical history and clinical assessment by the Investigator, and found eligible for topical application of the investigational products, as per study protocol.

Vulnerable participants were excluded, including children, lactating mothers, elderly individuals aged over 80 years, physically handicapped individuals, seriously ill participants, or those with mental impairment. Additional exclusion criteria excluded dermatological diseases, history of uncontrolled diabetes mellitus, known hypersensitivity to any components of the investigational products, history of drug or alcohol abuse within the preceding six months, participation in another investigational drug trial within 30 days prior to screening, or women of childbearing potential who were unwilling or unable to use an acceptable method of contraception during the study period.

Study Endpoints

The primary efficacy endpoints evaluated of the onset, duration, and magnitude of analgesic response, including time to onset of pain relief, time to onset of sensory effects, time to complete pain relief from pain and time to reapplication, assessed using the Numeric Pain Rating Scale (NPRS). Pain intensity at rest and during movement was assessed at predefined intervals up to 8 hours post-dose. Changes in musculoskeletal and joint pain intensity from baseline to Week 2 were evaluated using the Visual Analogue Scale (VAS; 0–100 mm). Patient-reported outcomes included treatment satisfaction and product acceptability, assessed using 5-point and 7-point Likert scales. Additional efficacy measures included rescue medication use, change in health-related quality of life (SF-12), and changes in inflammatory biomarkers (C-reactive protein and erythrocyte sedimentation rate) in participants with arthritis.

The secondary endpoint was safety and tolerability, assessed by monitoring treatment-emergent adverse events throughout the study period.

Statistical analysis

Descriptive statistics were given for baseline characteristics like age, gender, any adverse events and tolerability profiles. All the results were evaluated and compared between the test and comparator, by SPSS software version 23.0. A statistically significant improvement ($P<0.05$) in the clinical parameters along with the study specific efficacy parameter at the end of the study was observed which proved the safety and efficacy.

Results

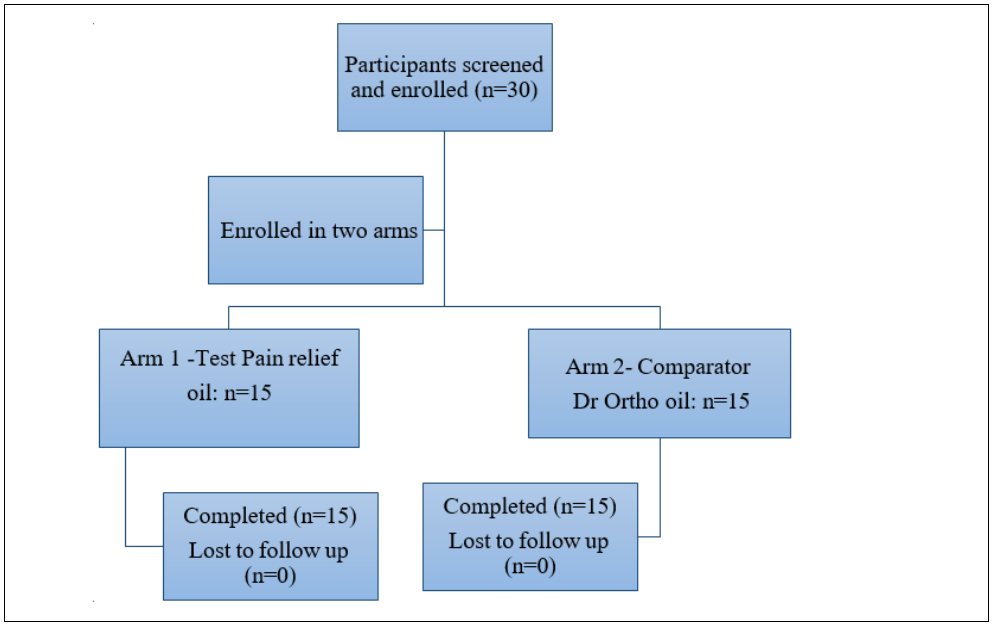

Fig 1: Flow Chart

A total of 30 participants were enrolled and randomized into two study arms, with 15 participants in each group (Pain Relief Oil with 6% Cannabis Extract (T) and Dr. Ortho Oil (C)), and all participants completed the study without dropouts (Fig.1). Baseline gender distribution was comparable between the groups, with males and females adequately represented. The age distribution was similar across both arms, with the majority of participants belonging to the 31–40 years age group, followed by the 21–30 years group. Overall, analyses of gender, age, and BMI confirmed that the study groups were demographically comparable at baseline.

The time to onset of pain relief was slightly shorter in the Pain Relief Oil with 6% Cannabis Extract (T) group compared to the Dr. Ortho Oil (C) group; however, the difference was not statistically significant ($p = 0.246$). A rapid onset of analgesia is clinically relevant, as faster pain relief is often associated with improved patient satisfaction and perceived treatment effectiveness [6]. The onset of cooling sensation occurred earlier with Pain Relief Oil with 6% Cannabis Extract (T) than with Dr. Ortho Oil (C), although this difference did not reach statistical significance ($p = 0.25$); cooling sensations are known to activate transient receptor potential (TRP) channels, providing a soothing sensory effect that complements analgesic activity [7]. With respect to complete pain relief, both treatment groups demonstrated limited achievement within the observation period observed, with no statistically significant difference between groups ($p = 0.323$). The time requirement for a second application and the overall duration of analgesic action were comparable between the two products ($p = 0.882$ and $p = 0.547$, respectively), consistent with a localized and time-limited effects characteristic of topical pain-relief formulations [8]. (Table: 1)

Assessment of pain reduction at rest revealed no statistically significant differences between the two groups across all evaluated time points. Both treatments produced a progressive reduction in pain scores from baseline, supporting their effectiveness in localized musculoskeletal pain management [9]. Similarly, pain reduction during movement was comparable between Pain Relief Oil with 6% Cannabis Extract (T) and Dr. Ortho Oil (C) at all time points assessed, indicating equivalent efficacy in alleviating movement-induced pain, an important indicator of functional improvement.

Within-group analysis using repeated measures ANOVA demonstrated a statistically significant reduction in pain scores over time in both treatment arms ($p = 0.0001$), indicating sustained analgesic efficacy with continued topical application. These findings are consistent with previous evidence supporting the effectiveness of topical formulations in providing consistent pain relief when applied at appropriate intervals [10].

Both Pain Relief Oil with 6% Cannabis Extract (T) and Dr. Ortho Oil (C) demonstrated a statistically significant reduction in joint pain intensity from baseline to post-treatment ($p = 0.0001$ for both groups), highlighting the effectiveness of the two topical formulations in alleviating joint-related pain. These findings are consistent with previous evidence supporting the clinical utility of topical analgesics in the management of joint pain [11] (Table: 2 & 3). User acceptability assessments showed that both products were rated comparably for ease of application and spreading**,** with Pain Relief Oil with 6% Cannabis Extract (T) receiving slightly higher scores for ease of spreading, although the difference was not statistically significant ($p = 0.093$). Additionally, stickiness and greasiness ratings were similar between the two products, with no significant differences observed. These sensory attributes play an important role in user satisfaction and treatment adherence, further supporting the acceptability of both formulations for regular topical use [12, 13] (Table: 4, 5). There was no rescue medication used by the participants throughout the study period. Participant overall satisfaction assessed using a 7-point Likert scale showed a statistically significant improvement at Day 14 (post-study) compared to baseline. Between-group analysis demonstrated significantly greater improvement in satisfaction scores in the Pain Relief Oil group compared with the Dr. Ortho Oil group. (Table: 6)

Inflammatory Biomarkers

Both produced a statistically significant reduction in erythrocyte sedimentation rate **(**ESR**)** from baseline to the end of the study ($p = 0.0001$ for both groups), with no significant difference between treatments, indicating comparable anti-inflammatory effects. Reduction in ESR reflects a decrease in systemic inflammatory activity and is consistent with the known anti-inflammatory properties of topical NSAID formulations [14]. C-reactive protein (CRP) levels showed a downward trend in both treatment groups; however, the changes did not reach statistical significance (Pain Relief Oil: $p = 0.145$; Dr. Ortho: $p = 0.222$). As CRP is a sensitive marker of inflammation, these findings suggest that while both products may confer modest systemic anti-inflammatory benefits, their primary therapeutic effects are likely localized rather than systemic [15]. (Table: 7)

Discussion

The present study demonstrates that Pain Relief Oil with 6% Cannabis Extract (T) and Dr. Ortho Oil (C) show comparable clinical performance across key time-related efficacy parameters, including onset of analgesia, sensory response, and duration of action. Although Pain Relief Oil with 6% Cannabis Extract exhibited a numerically faster onset of pain relief and cooling sensation, these differences were not statistically significant, indicating that both formulations provide a similar speed of therapeutic effect. Rapid onset of analgesia is an important factor influencing patient satisfaction and perceived treatment benefit, particularly in musculoskeletal pain conditions.

The limited achievement of complete pain relief observed in both treatment groups highlights the complex and multifactorial nature of musculoskeletal pain, which is influenced by individual pain thresholds, disease characteristics, and variability in response to topical therapies. This finding is consistent with existing evidence that topical analgesics primarily offer localized symptomatic relief rather than complete resolution of pain, especially in chronic pain states.

The similarity in time to reapplication and overall duration of analgesic action between the two products further indicates that Pain Relief Oil with 6% Cannabis Extract (T) and Dr. Ortho Oil (C) possess comparable pharmacodynamic profiles, characteristic of topical pain-relief formulations. These localized and time-limited effects observed align with established literature on topical nonsteroidal anti-inflammatory and counterirritant-based

therapies designed to provide targeted pain relief while minimizing systemic exposure.

Overall, these findings support the conclusion that Pain Relief Oil with 6% Cannabis Extract (T) is clinically comparable to Dr. Ortho Oil (C) with respect to onset, duration, and sensory effects, reinforcing its suitability as an effective topical option for the management of musculoskeletal pain.

Conclusion

Both Pain Relief Oil with 6% Cannabis Extract (T) and Dr. Ortho Oil (C) demonstrated comparable efficacy in reducing pain and inflammation, both at rest and during movement. However, Pain Relief Oil with 6% Cannabis Extract (T) exhibited a slightly faster onset of action and was rated higher for ease of spreading, suggesting a more user-friendly application. Additionally, while both products significantly reduced ESR, a key marker of systemic inflammation, Pain Relief Oil with 6% Cannabis Extract (T) showed a numerically greater improvement in user perception scores, reinforcing its acceptability.

Although CRP reductions were not statistically significant, the observed trends indicate that both products provide modest systemic anti-inflammatory benefits. The findings align with existing literature on the effectiveness of topical analgesics and NSAIDs for managing musculoskeletal pain. Given its slightly faster action and superior ease of application, Pain Relief Oil with 6% Cannabis Extract (T) may offer a preferable choice for users seeking effective and convenient pain relief.

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Conflicts of Interest: None

Table 1: Assessment of Pain relief at various time points (numeric pain rating scale)

Variables (units)	Pain Relief Oil (n=15)	Dr Ortho oil (n=15)	P-value
	Mean ± SD	Mean ± SD	
Time to Pain Relief /Onset of Cooling in seconds	77.67± 17.41	85.67± 19.536	0.246
Complete Relief	N/Ap	N/Ap	N/Ap
Time of need for 2nd application of product	10.73± 3.575	11.33± 14.744	0.879
Duration of action: (A-B)	10.73± 3.575	11.33± 14.744	0.879

Table 2: Reduction in pain score at Rest

Time Points	Pain Releif Oil (n=15)	Dr Ortho (n=15)	P-value (Between groups)
	Mean ± SD	Mean ± SD	
0 Second	5.2± 1.014	5.2± 0.862	0.99
30 Seconds	5.2± 1.014	5.2± 0.862	0.999
1 Minute	4.8± 1.373	5.07± 1.1	0.562
2 Minutes	4.33± 1.175	4.27± 0.884	0.862
5 Minutes	4.07± 1.163	4.2± 0.862	0.724
10 Minutes	3.8± 1.373	3.87± 0.99	0.88
15 Minutes	3.47± 1.246	3.4± 0.986	0.872
30 Minutes	3.33± 1.113	3.33± 0.816	0.999
45 Minutes	2.87± 1.457	2.93± 1.223	0.893
60 Minutes	2.6± 1.404	2.6± 1.121	0.999
75 Minutes	2.53± 1.302	2.53± 0.99	0.91
90 Minutes	2.2± 1.74	2.27± 1.438	0.759
105 Minutes	1.93± 1.907	1.73± 1.624	0.516
120 Minutes	2.43± 1.742	2± 1.633	0.625
3 Hours	3± 1.195	2.8± 1.014	0.501
4 Hours	3.47± 1.187	3.2± 0.941	0.848
5 Hours	3.67± 1.047	3.6± 0.828	0.999
6 Hours	3.87± 0.99	3.87± 0.915	0.863
7 Hours	3.93± 1.163	3.87± 0.915	0.863
8 Hours	3.93± 1.163	3.87± 0.915	0.999
p- value (Within group)	0.0001	0.0001	

Table 3: Reduction in pain score at Movement

	Pain Releif Oil (n=15)	Dr Ortho (n=15)	P-value
Time Points	Mean ± SD	Mean ± SD	(Between groups)
0 Second	5.27± 1.033	5.27± 0.884	0.999
30 Seconds	5.27± 1.033	5.27± 0.884	0.999
1 Minute	5.2± 0.941	5.2± 0.862	0.999
2 Minutes	4.93± 1.033	4.87± 1.125	0.867
5 Minutes	4.4± 1.183	4.53± 1.187	0.76

10 Minutes	4.27± 1.033	4.33± 0.976	0.857
15 Minutes	4.2± 0.941	4.27± 0.799	0.836
30 Minutes	3.8± 1.082	3.87± 1.06	0.866
45 Minutes	3.47± 1.246	3.6± 1.056	0.754
60 Minutes	3.4± 1.121	3.47± 0.915	0.86
75 Minutes	3.13± 1.246	3.2± 1.146	0.88
90 Minutes	2.8± 1.568	3± 1.254	0.702
105 Minutes	2.67± 1.718	2.73± 1.624	0.914
120 Minutes	3.07± 1.387	2.87± 1.506	0.708
3 Hours	3.27± 1.534	3.07± 1.668	0.735
4 Hours	3.6± 1.454	3.4± 1.682	0.73
5 Hours	3.6± 1.454	3.4± 1.682	0.73
6 Hours	3.6± 1.454	3.4± 1.682	0.73
7 Hours	3.67± 1.589	3.4± 1.682	0.659
8 Hours	3.67± 1.589	3.4± 1.682	0.855
p- value (Within group)	0.0001	0.0001	

Table 4: Joint/Musculo skeletal pain intensity measured by Pain VAS Scale (0-100 mm)

Variables	Pain Releif Oil (n=15)	Dr Ortho (n=15)
	Mean ± SD	Mean ± SD
Baseline	62± 9.411	62.67± 10.328
Post Study	35± 11.18	36± 9.856
p-value (Between groups)	0.0001	0.0001

Table 5: User Perception on a 5-Point Likert Satisfaction Scale

Variables	Pain Releif Oil (n=15) (Mean ± SD)		Dr Ortho (n=15) (Mean ± SD)		p- value Post study comparison (Between groups)
	Day 1	Post Study	Day 1	Post Study	
Ease of application	4.91± 0.75	3.73± 0.594	3.92± 0.52	3.67± 0.488	0.739
Stickiness	4.26± 0.78	2.73± 0.594	2.92± 0.62	2.87± 0.516	0.517
Greasiness	3.96± 0.85	3± 0.655	3.72± 0.52	3± 0.655	0.999
Ease of spreading	4.9 ± 0.23	4.27± 0.458	4.26± 0.58	4± 0.378	0.093

(1) Strongly disagree; (2) Disagree; (3) Neither agree nor disagree; (4) Agree; (5) Strongly

Table 6: Participant's overall satisfaction for pain relief on a 7- point Likert Satisfaction scale

Study Arm	Overall response (Post Study)		p-value (within group)
	Mean ± SD		
	Day 1	Post Study	
Pain Releif Oil (n=15)	5.0 ± 0.65	3.4 ± 0.632	0.0001
Dr Ortho Oil (n=15)	6.06 ± 0.20	2.0 ± 0.756	0.0001
P Value (Between groups)	0.006	<0.0001	

(1) Extremely satisfied; (2) Very satisfied; (3) Satisfied; (4) Neither satisfied nor dissatisfied; (5) Dissatisfied; (6) Very Dissatisfied; (7) Extremely Dissatisfied

Table 7: Inflammatory Markers

Variables	Study Visit	Pain Relief Oil	Dr Ortho Oil	P-value (Between groups)
		Mean ± SD	Mean ± SD	
ESR	Baseline	27.87± 13.341	31.27± 9.051	0.421
	Post Study	21.2± 10.051	23.4± 7.029	0.297
p value (within groups)		0.0001	0.0001	-
CRP	Baseline	8.76± 4.1822	9.013± 4.2399	0.845
	Post Study	7.98± 3.2881	8.427± 3.2618	0.79
p value (within groups)		0.145	0.222	-

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