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Dr. Kenneth Orbeck
DO, Regenerative Medical Institute, 503 Roper Creek Dr., Greenville, South Carolina

Dr. Imdad Ullah
MBBS, Khyber Medical College, Peshawar, Pakistan

Corresponding Author:
Dr. Imdad Ullah
MBBS, Khyber Medical College, Peshawar, Pakistan

Proleevamax and its role in management of chronic pain and inflammation: Clinical efficacy and trial outcomes

Dr. Kenneth Orbeck and Dr. Imdad Ullah

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Abstract

Background and Aim: This clinical trial aimed to assess the clinical efficacy of Proleevamax™, a new nutraceutical supplement for the management of chronic inflammatory disorders and pain. This supplement, enriched with amino acids, supplements, and vitamins, is formulated to address neurotransmitter imbalances in chronic inflammatory conditions. The study was designed to assess safety and clinical efficacy in patients with those conditions.

Methods: The study involved 12 male and female patients with various chronic conditions. The participants were selected based on the preset criteria outlined in the patient information. Patients were given Proleevamax™ capsules and instructed to take 4 capsules per day, with or without food for 8 weeks. It was at the patient's discretion whether it was taken 4 QD or 2 BID. The efficacy of Proleevamax in reducing pain and inflammation was then evaluated. This includes tracking changes in pain scores using the McGill Pain Survey and monitoring the hs-CRP test levels. Patients completed the patient information form and the McGill pain survey at the start of therapy, at 30 and at 60 days. Laboratory tests are done at baseline, 4 weeks, and 8 weeks.

Results: (Mean CI 95%) The Proleevamax Clinical trial significantly reduced C-reactive protein levels and decreased pain intensity among participants (with a P value less than 0.05 in the change), with a P value of 0.042. This indicates that Proleevamax™ may be effective in managing chronic pain and inflammation. While the results look encouraging, further studies are recommended to confirm these results.

Conclusion: Proleevmax™ has reduced pain and inflammation in the patients, as demonstrated in the trial. It reduced the C-reactive protein levels and improved pain intensity among patients.

Keywords: Proleevmax™, chronic fatigue, arthritis, clinical efficacy, clinical trials, chronic inflammatory diseases

Introduction

High-sensitivity C-reactive protein (hs-CRP) is a marker of inflammation that indicates chronic inflammation from arthritis, colitis, myocardial infarction, stroke, and sudden cardiac death [1, 2].

In the USA, almost 51.6 million people (21%) had chronic pain and inflammation from 2019 to 2021 [3]. Normal serum level for hs-CRP are between 1-3mg/L. When there is an infection, trauma, or other inflammatory conditions, they generally rises to 10 mg/L [4]. Chronic inflammatory diseases pose a significant threat to public health, contributing to a substantial portion of global morbidity and mortality [5]. As individuals age, their immune systems become less resilient, making them susceptible to various diseases and inflammatory conditions. Chronic inflammation, fatigue, and associated diseases, such as diabetes mellitus, cardiovascular diseases, arthritis, and chronic obstructive pulmonary disease (COPD), are on the rise globally, necessitating effective management strategies for chronic inflammation [6, 7]. When left untreated, may have severe result. Inflammation from osteoarthritis, often seen as non-inflammatory, can cause immune-related inflammation, especially in the knee [8]. Harmful stimuli such as pathogens, irritants, and damaged cells cause inflammatory syndromes. Chronic inflammation, when left untreated, may have severe results. For example, osteoarthritis is commonly seen as a non-inflammatory condition, but it has the potential to ultimately cause immune-related inflammation, especially in the knee [9]. Chronic inflammatory conditions demand lifestyle modifications, including a balanced diet rich in essential nutrients, to mitigate symptoms and reduce the risk of complications [9, 10].

However, even with an adjusted diet change, that is not enough. Proleevamax™ offers a vegetarian capsule containing a proprietary blend of essential amino acids, vitamins, and other nutrients important for immune system support and nutritional well-being. The focus of Proleevamax™ is on inflammatory conditions. Harmful stimuli such as pathogens, irritants, and damaged cells cause inflammation [11]. Proleevamax™ is also formulated with such ingredients as 5-HTP, GABA, and Panax Ginseng to minimize depression and fatigue, common with people with chronic inflammation and pain. Proleevamax™ modulates the neurotransmitters and prevents oxidative stress, produces a calming effect, aids muscle, provides energy, and strengthens the body [12]. The supplement addresses the imbalance of neurotransmitters in the brain associated with chronic inflammatory conditions. Through its unique blend of active ingredients, including 5-HTP, Choline L-Bitartrate, GABA, and various extracts, Proleevamax™ aims to restore and maintain average neurotransmitter balance, relieving pain, inflammation, and fatigue. This paper shall dive into the effects and findings of Proleevamax™ on patients suffering from chronic inflammatory conditions, such as arthritis and chronic fatigue. Moreover, the supplement's safety profile is also discussed, highlighting its minimal side effects and contraindications. Clinical efficacy and trial outcomes are presented to emphasize the potential of Proleevamax™ as a supplementary option in managing chronic inflammatory diseases, offering a promising avenue for improved patient outcomes.

The aging process exposes the human body to an increased susceptibility to infectious agents, diseases, and chronic inflammatory conditions [13]. Among the health challenges associated with aging, chronic inflammation is a prominent contributor to various diseases and comorbidities [14]. This paper focuses on the escalating prevalence of chronic inflammatory diseases, such as diabetes mellitus, cardiovascular diseases, arthritis, and COPD, and their impact on public health.

Management and treatment protocols for chronic inflammatory diseases typically involve lifestyle modifications, emphasizing a balanced diet and healthy habits [15]. Studies have investigated that consuming natural diets, especially green leaf foods, can reduce the Serum C-Reactive Protein (CRP) level and, in turn, reduce inflammation and other chronic diseases [16]. While these interventions are crucial, there is a growing recognition of the need for supplementary options to address deficiencies and optimize immune function. Proleevamax™ presents a sensible solution.

This paper explores the landscape of chronic inflammatory diseases, emphasizing their increasing incidence and associated complications. It then discusses the traditional approaches to managing these conditions, underscoring the role of lifestyle modifications and dietary interventions. The spotlight then shifts to Proleevamax™ as a supplementary option, elucidating its composition, mechanism of action, metabolism, and recommended dosage. Clinical efficacy and trial outcomes are discussed, providing a comprehensive overview of Proleevamax™ and its potential to enhance the management of chronic inflammatory diseases.

Methodology

Study design: Twelve participants with chronic pain, inflammation, and arthritis were recruited for the study between April and June 2023. The trial study aimed to determine the effect of the supplement Proleevamax™ on patients having chronic pain, inflammation from various arthritic diseases. For this purpose, some patients with serious problems like stiffness, joint pains, ulcerative colitis, arthritis, and knee osteoarthritis were taken for the study. The survey measured the discomfort level from mild to distressing regarding their hs-CPR values, indicating inflammation.

Table 1: Number of Participants

Included	12	100.0%
Excluded	0	0.0%
Total	12	100.0%

Demographic Characteristics

The mean age of the participants was 57±12.62 years. The minimum age was 24, and the maximum age was 76. Subgroup analysis revealed a mean age of 59.85±9.77 for males and 53.5±15.01 for females.

Intervention

The trial employed Proleevamax™ as the therapeutic intervention. Proleevamax™ was tested on the participants. For effectiveness, the participants were advised to take 4 capsules daily for 8 weeks. Each capsule contained 13 different ingredients with a value of 2653 mg per serving. The physician had instructed to have the laboratory draw and collect each participant's blood sample to check the hs-CRP level (normal < 3 mg/L for high sensitivity CRP in months from April to June 2023) the day before starting Proleevamax™. Baseline blood samples were taken to the laboratory soon after the collection to avoid clotting and check for accurate results. The process was repeated at 30 days and 60 days. In addition to hs-CRP level, the demographic characteristics of age and sex were assessed. The trained staff measured weight and body mass. Blood pressure was measured for systolic and diastolic blood pressures. The information on the pain level was recorder before the start of taking Proleevamax™, after 30 days of taking Proleevamax™, and after 60 days. The information was obtained using a standard questionnaire administered by the trained staff and the self-reported participants.

Table 2: Characteristics of Participants

	N	Minimum	Maximum	Mean	Std. Deviation
Gender	12	1	2	1.50	.522
Age	12	24	76	57.00	12.620
Pre_PPI	12	0	3	2.00	1.128
Post_PPI	12	0	2	.92	.793
hs_CRP_0_week	12	1.2	6.4	3.442	1.4349
hs_CRP_8_week	12	.80	4.60	2.1917	1.10820
Valid N (listwise)	12				

PPI = Present pain intensity (0 = No pain, 1= Mild, 2 = Moderate, 3 = Severe) One-way repeated ANOVA

Outcome Measures

The primary outcome measures were pre- and post-intervention C-reactive protein (CRP) levels. Baseline CRP levels were recorded before participants commenced Proleevamax™ with supplementation after 30 and 60 days. The outcomes of the participants of hs-CRP level were measured from the baseline base tests, and different results

were obtained at different intervals. The pain intensity from inflammation was measured by the McGill survey questionnaire, ranking from 0 to 1 for no pain to severe pain (Table 2).

Statistical Analysis: The difference in mean pre- and post-intervention CRP levels was analyzed using a paired T-test. The statistical significance level was set at $P < 0.05$. One-way repeated measures ANOVA was used to measure the CRP level at different intervals. The overall change in CRP levels and the change in men's CRP levels were examined separately. The analysis revealed a statistically significant difference in the change of CRP levels, with a P-value of 0.042 for the combined population and 0.021 for males.

Table 3: T-Test, paired two sample for means for men

	Pre	Post
Mean	3.80	2.07
Variance	3.40	1.13
Observations	6.00	6.00
Pearson Correlation	0.52	
Hypothesized Mean Difference	-	
df	5.00	
t Stat	2.69	
P(T<=t) one-tail	0.02	
t Critical one-tail	2.02	
P(T<=t) two-tail	0.04	
t Critical two-tail	2.57	

Table 4: T-Test, paired two sample for means for women

	Pre Intervention	Post-intervention
Mean	3.08	2.97
Variance	0.83	3.58
Observations	6.00	6
Pearson Correlation	0.64	
Hypothesized Mean Difference	-	
DF	5.00	
T-Stat	0.19	
P(T<=t) one-tail	0.43	
t Critical one-tail	2.02	
P(T<=t) two-tail	0.86	
t Critical two-tail	2.57	

Table 5: T-Test, paired two sample for means for men + women

	Pre intervention CRP	Post intervention CRP
Mean	3.44	2.52
Variance	2.06	2.36
Observations	12.00	12.00
Pearson Correlation	0.35	
Hypothesized Mean Difference	-	
DF	11.00	
t Stat	1.90	
P(T<=t) one-tail	0.04	
t Critical one-tail	1.80	
P(T<=t) two-tail	0.08	
t Critical two-tail	2.20	

Table 6: Participant Results

Subject	Pre-CRP	Post-CRP	Pre-PPI	Post-PPI	Subject's Clinical Presentation
1	6.4	3.7	2	1	↓ CRP, chronic pain, fatigue
2	4.3	2.2	0	0	↓CRP
3	3.6	2.8	3	1	Joint pain, stiffness, swelling
4	2.4	1.3	2	1	None stated
5	3.1	1.3	3	0	Back, hip and knee pain
6	4.9	.8	3	2	↓CRP, shoulder and knee pain
7	1.2	1.6	3	1	None stated
8	3.6	4.6	2	2	Neck, back, sciatic pain
9	2.4	2.2	0	0	None stated
10	1.8	2.6	2	2	Hip and shoulder pain
11	4.4	5.9	0	1	↑CRP due to thyroid issues
12	3.2	1.2	2	1	Lower back, joint pain

Results and Conclusion

The study used a specific number of participants for the trial, but those were reliable and meant to derive a true picture of the product. To discern the clinical relevance of the product. The participant's CRP level was measured at the start of the trial and calculated and recorded for the different kinds of inflammation conditions, that is, fatigue, chronic pain, inflammation for celiac disease, joint pain, stiffness, swelling, shoulder and knee pain from scar tissues, and arthritis. Among them, the highest number of CRP values were determined for chronic pain and fatigue (6.4), then shoulder and knee pain (4.9) following inflammation from celiac disease (4.3). The CRP level went down considerably, by 50%, after 8 weeks of taking Proleevamax. The conditions and pain improved by more than 50% also.

The use of Proleevamax has had positive effects on the participants and improved their CRP levels. In addition to CRP levels, the study assessed pain intensity levels among participants. Improvements were observed, with pain moving from distressing to discomforting and from mild and discomforting to simply mild in eight patients. Furthermore, two patients reported a complete absence of pain. One patient did experience a decrease in stomach bloating, and another observed an improvement in joint stiffness while taking Proleevamax™. Two patients maintained the same pain intensity throughout the study due to specific conditions not indicated for Proleevamax™ use.

The trial provided preliminary evidence supporting the efficacy of Proleevamax™ in managing chronic pain and inflammation associated with various diseases. The intervention demonstrated a statistically significant reduction in CRP levels, indicating its potential therapeutic impact on chronic inflammatory conditions. These findings suggest that Proleevamax™ may serve as a valuable supplementary option for individuals seeking relief from chronic pain and inflammation.

Conflict of Interest

Not available.

Financial Support

Not available.

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