

# Efficacy of Plai Cream in Adult Patients with Muscle Strain: A Randomized, Double-Blind, Placebo-Controlled Trial

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**Background:** Nonsteroidal anti-inflammatory drugs are a standard treatment option for muscle strain; however, side effects persist.

**Objective:** This clinical trial was designed to compare the efficacy of Plai cream compared to placebos in adult patients with muscle strain.

**Material and Method:** In this randomized, double-blind, placebo-controlled trial, 140 participants aged over 18 years with muscle strain were randomized to receive either Plai cream ( $n = 70$  patients, treatment group) or placebos ( $n = 70$  patients, control group). Outcome assessments included the visual analog scale (VAS), quality of life (QoL), the amount of remaining cream, and the number of acetaminophen tablets used.

**Results:** After 2 weeks, the mean pain scores following treatment with both Plai cream and placebos in patients with muscle strain decreased from baseline to the end of the study at week 2. However, no significant difference for VAS score was found. The QoL of the two groups showed improvements in QoL as witnessed by increased mean QoL scores from baseline to week 2; however, these differences were not statistically significant. In general, mean QoL scores above 50 indicate good quality of life. The amount of Plai cream used reduced from baseline to week 2, but no significant difference in the amount of cream remaining was found between the two groups at each visit. Similarly, the number of acetaminophen tablets used was not statistically different between the treatment and control groups.

**Conclusion:** There was no difference in pain reduction in the 2-week period between patients with muscle strain using Plai cream and those given placebos, but Plai cream tended to reduce pain in the long term. No side effects were found from Plai cream, so this non-invasive treatment may be offered to patients.

**Keywords:** Zingiber cassumunar Roxb, Plai cream, Muscle strain

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Muscle strain (muscle pull or tear) is a common injury problem, in particular among people who participate in sports or use their muscles quite often. Muscle strains appear when a muscle is stretched over its limit, tearing the muscle fibers; this causes pain and may limit movement within the affected muscle group, and once a strain occurs, the muscle is vulnerable to re-injury<sup>(1-3)</sup>. Mild to moderate strains can be treated at home with ice, heat, and anti-inflammatory medications,

and physicians normally recommend taking a break from the activities that caused the problem<sup>(4)</sup>. A cold pack is recommended to be used for a while, several times a day. To prevent additional swelling, the strain area should be lightly wrapped in a soft bandage or ace wrap, and the leg should be raised above the level of the heart. Severe strains or tears may require medical treatment, intramuscular administration and drug therapy, including oral and topical analgesics. The drugs which have been recommended for pain relief include paracetamol (acetaminophen) and nonsteroidal anti-inflammatory drugs (NSAIDs); however, the systemic side effects of NSAIDs have become a source of increasing concern, and caution must be taken when using them<sup>(5-8)</sup>. Alternatively, some medicinal plants or

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alternative medicines have been used for pain relief<sup>(9)</sup>. A double-blinded, randomized controlled study of the effectiveness of willow (*Salix*) bark extract, which is widely used in Europe, for the treatment of 210 patients with low-back pain, found that the proportions of pain-free patients in the last week of treatment were 39% in the group receiving high-dose extract, 21% in the group receiving low-dose extract, and 6% in the placebo group ( $p < 0.001$ ). The response in the high-dose group was evident after only 1 week of treatment<sup>(10)</sup>. Similar results were achieved in a systematic review of 14 RCTs performed to determine the effectiveness of herbal medicine for non-specific low-back pain, which found that some herbs such as *C. frutescens* (*Cayenne*) reduced pain more than placebos. It seems that *H. procumbens*, *S. alba*, *S. officinale* L., *S. chilensis*, and lavender essential oil reduce pain more than placebos, but the evidence for these substances was of only moderate quality. Additional well-designed large trials are needed to compare the efficacy of these herbal medicines with that of standard treatments<sup>(11)</sup>.

Plai or *Zingiber cassumunar Roxb* is one of the most commonly used medicinal plants in Asian folk remedies for muscle strain, joint problems, and pain<sup>(12)</sup>. Plai is an analgesic that has long been regarded by Thai massage therapists as one of those oils, which are necessary to combat joint and muscle problems. It is applied for problems such as aches and pains, inflammations, joint problems, muscle spasms, sprains and strains. Plai is of the same family as ginger but has different properties and more intense actions. A double-blinded randomized controlled study by Laupattarakasem W (1993)<sup>(13)</sup> extracted essential oil from Plai and developed it into a topical cream containing 14% Plai oil for reducing pain and swelling of the ankle. Using Plai cream twice daily remarkably reduced the severity of swelling. The author concluded that Plai cream is efficacious in reducing symptoms of ankle pain where joint stability has not been violated. The aim of the current study was to assess the efficacy of Plai cream in adult patients with muscle strain.

## Material and Method

### Study design and participants

This was a prospective, randomized, double-blind, placebo-controlled trial. Male and female orthopedic outpatients were recruited from June 2012 to February 2013 in Rajavithi Hospital. Inclusion criteria were: over 18 years; having been diagnosed with muscle strain; and presence of spontaneous pain (measured on a 10 cm visual analogue scale [VAS], ranging from 0

[no pain] to 10 [unbearable pain]). Exclusion criteria were patients who had ankle fracture or severe ankle sprain and were not considered amenable to treatment with topical NSAIDs alone. In addition, patients who used medication (other than the study cream and rescue medication [paracetamol]) for the treatment of complaints caused by the affected ankle or other inflammatory or painful conditions were also excluded from the study. Patients were randomly assigned to one of two parallel treatment groups according to the numerical order in which they were enrolled, using a computer-generated random assignment. The overall design of the study consisted of a 14-day treatment period. After the inclusion visit, patients were asked to measure VAS and quality of life (QoL) using the SF-36 Thai questionnaire. Patients were randomized to one of the following treatment regimens: Plai cream applied to the skin with the affected muscle strain region for 14 days; or B, placebo (no active ingredient), applied in the same manner for 14 days. Acetaminophen tablets were given to reduce pain in both groups, and all patients and investigators were blinded to treatment. The patients were examined at days 7 and 14 to measure VAS, SF-36, and both the amount of remaining Plai cream and the number of acetaminophen tablets used to relieve pain was recorded. This study was approved by the Rajavithi Hospital ethics committee, and patients provided written informed consent before their inclusion into the trial. The flow diagram of the study is shown in Fig. 1.

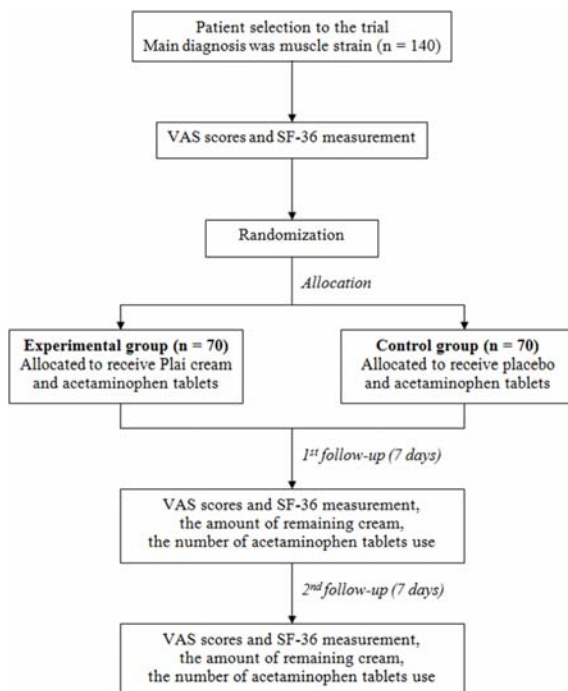
### Statistical analyses

All analyses were performed using the statistical program SPSS version 17.0. Data were presented as mean, standard deviation (SD), minimum, and maximum for continuous variables and number (%) for categorical variables. Baseline characteristics of the two groups were compared using the student t-test for quantitative variables and the Chi-square test for nominal variables. Repeated measure ANOVA were used to compare mean changes in VAS scores and QoL over time (day 7 and day 14). The level of statistical significance was set at  $p < 0.050$ .

## Results

### Population studied

140 participants were enrolled and 70 patients were randomized into each group. During the 14 days of follow-up, no patients withdrew. Demographic characteristics at the baseline for the two study groups were similar, as shown in Table 1.



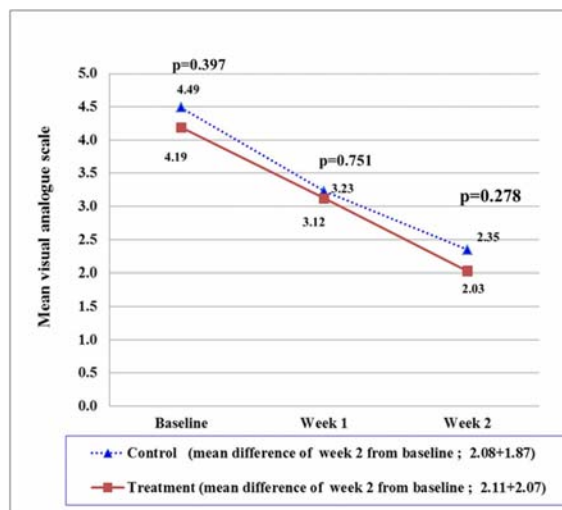
**Fig. 1** Flow diagram of the study.

**Table 1.** Baseline characteristics of the subjects

Characteristics	Groups		p-value
	Treatment (n = 70)	Control (n = 70)	
Gender n (%)			0.382
Male	8 (11.4)	5 (7.1)	
Female	62 (88.6)	65 (92.9)	
Age (years)			0.463
Mean ± SD	43.61±11.25	42.27±10.34	
BMI (kg/m <sup>2</sup> )			0.603
Mean ± SD	23.77±4.02	24.17±5.12	

### Efficacy

The mean pain scores following treatment with Plai cream (treatment) or placebo (control) in patients with muscle strain decreased from baseline to the end of the study at week 2 (Fig. 2); however, the differences between the treatment and control groups in pain scores were not significantly different at visits 1 and 2. The amount of Plai cream used reduced from baseline to week 2, but no significant difference in the amount of cream remaining was found in the two groups at each visit. Similarly, the number of acetaminophen



**Fig. 2** Change from baseline in mean pain scores following treatment with Plai cream (treatment) or Placebo (control) in patients with muscle strain.

tablets used was not significantly different in the treatment and control group.

The QoL scores in the two groups are presented in Table 2. The patients in both groups had significant improvement in QoL as witnessed by the increased mean QoL scores from baseline to week 2 (mean QoL scores above 50 indicate good quality of life). Regarding the QoL between groups, no significant difference was found in the quality of life from baseline to week 2. Intragroup comparisons showed a statistically significant difference in QoL by at least one visit meaning that QoL improved over time.

### Discussion

It has been claimed in the literature that the safety of herbal medicines has not been scientifically proven<sup>(14)</sup>. However, systematic reviews of 19 randomized placebo-controlled double-blind studies reported that herbal anti-inflammatory drugs were more effective than placebos in the treatment of osteoarthritis and rheumatic pain<sup>(15)</sup>. Similar observations were documented in a systematic review of 14 RCTs for low-back pain relief using herbal medicines<sup>(11)</sup>. Moreover, a 6-week RCT study performed to assess the efficacy of ginger in decreasing pain in OA patients, found that administering ginger capsules (255 mg of extract drawn from 2,500-4,000 mg of dried ginger rhizome) twice daily decreased patients' pain symptoms when standing and walking 50 feet<sup>(16)</sup>.

This prospective, randomized, double-blind,

**Table 2.** The quality of life in the treatment and control groups

Factors	Group		p-value (between group)
	Treatment (n = 70) mean ± SD	Control (n = 70) mean ± SD	
Total score SF 36			
Baseline (week 0)	55.56±13.90	56.20±13.69	0.796
Week 1	57.30±13.43	62.17±13.72	0.059
Week 2	61.81±14.88	64.46±15.73	0.332
The p-value (within group)			
Week 0 vs. week 1	0.456	<0.001	
Week 0 vs. week 2	<0.001	<0.001	
Week 1 vs. week 2	0.003	0.332	

Significant at  $p < 0.050$

placebo-controlled study was aimed at assessing the efficacy of Plai cream compared with placebos in reducing pain resulting from muscle strain. The main efficacy criterion was a reduction in pain scores in the first week of the treatment. After one week, pain relief improved and continued to do so throughout the period of the trial. The decrease in pain is considered clinically relevant. The alleviation of their pain and other symptoms in the Plai (treatment) group were comparable with the findings of previous research<sup>(11,13,17)</sup>. Another study showed that 14% Plai oil can be used to reduce pain and swelling in the ankle: the use of Plai cream twice daily significantly reduced the severity of swelling<sup>(13)</sup>. In addition, a systematic review of 14 RCTs to determine the effectiveness of herbal medicine for non-specific LBP, found that some herbs such as *C. frutescens* (*Cayenne*) reduce pain more than placebos. It seems that *H. procumbens*, *S. alba*, *S. officinale* L., *S. chilensis*, and lavender essential oil reduce pain more than placebos, but the evidence for these substances was of only moderate quality. Additional well-designed large trials are needed to evaluate these herbal medicines against standard treatments<sup>(11)</sup>.

In total, 70 patients in the treatment group and 70 patients in the placebo group took at least one tablet (range 1-6 tablets) of rescue medication for muscle strain over the treatment period. There was no statistical significance in between-group differences in the number of tablets taken, implying that the number of tablets taken was not related to the effects of treatment.

The quality of life (QoL) of the patients in the two groups showed significant improvement as witnessed by the increased mean QoL scores from

baseline to week 2. Although, no significant difference in QoL between the two groups was found, the QoL in the same group improved by 1 week at least and continued to do so throughout the trial period. A similar result was observed by Altman, 2001 who reported that administering ginger capsules twice daily decreased patients' pain symptoms when standing and walking 50 feet; however, it did not seem to significantly improve overall functionality, in particular the quality of life, which remained equal between the patients who received ginger extract and those given placebos<sup>(16)</sup>. The present study is not in agreement with a study by Niempoog<sup>(17)</sup>, which reported that both Diclofenac gel and combinations of extract of ginger and Plai (Plygersic), achieved significant improvements in pain relief, alleviated symptoms of decreased range of motion, raised patients' ADL scores, enabled increased sports activities, and enhanced patients' quality of life when assessed by the Knee Injury and Osteoarthritis Outcome Score at 2 through 6 weeks of the entire treatments. One possible explanation for the difference in these findings may be the present study's short follow-up period of only 2 weeks.

In conclusion, the efficacy of Plai cream for the treatment of muscle strain was better than that of placebos under randomized, double-blind, placebo-controlled conditions. Plai cream was also well tolerated, and can, therefore, be used for the relatively rapid relief of the symptoms of acute soft tissue injuries, and it may assist in restoring patients' mobility.

#### What is already known on this topic ?

Plai cream is used to relieve muscular aches, pain and sprains. This clinical trial aimed to compare

the efficacy of Plai cream with that of placebos in patients with muscle strain. The efficacy of Plai cream for the treatment of muscle strain was better than that of placebos. Plai cream can, therefore, be used for the relatively rapid relief of the symptoms of acute soft tissue injuries. Plai cream may also apply in restoring patients' mobility.

#### **What this study adds ?**

This study was one of the few studies that prospectively assessed the efficacy of Plai cream for the treatment of muscle strain. Reduction of pain after the trial is considered clinically relevant.

#### **Acknowledgement**

This study was supported by the research fund of Rajavithi Hospital. The authors wish to thank all the participants who took part in the trial. The authors are grateful to the staffs in the Division of Medical Research, Department of Research and Technology Assessment, Rajavithi Hospital for supportive assistance.

#### **Potential conflicts of interest**

None.

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## ประสิทธิภาพของครีมไพลในการรักษากล้ามเนื้อเคล็ด ข้อ ขอก

สุกชม ซีเจริญ, ธเนศ พัฒนะวิริยะศิริกุล, จารุวรรณ หน้มนี่, กัญญา จันทร์พล

ภูมิหลัง: การรักษาอาการเคล็ดข้อขอกกล้ามเนื้อมักใช้ยากลุ่ม Nonsteroidal anti-inflammatory drugs (NSAIDs) แต่ก็มีอาการข้างเคียง

วัตถุประสงค์: การศึกษาเพื่อเปรียบเทียบประสิทธิภาพของครีมไพลและยาหลอกในการรักษากล้ามเนื้อเคล็ด ข้อ ขอก

วัสดุและวิธีการ: การศึกษาทดลองแบบสุ่มติดตามไปข้างหน้าโดยเปรียบเทียบ 2 กลุ่ม ผู้ป่วยอายุมากกว่าหรือเท่ากับ 18 ปี ขึ้นไปที่ได้รับการวินิจฉัยมีอาการเคล็ด ข้อ ขอก กลุ่มศึกษาได้รับครีมไพล และกลุ่มควบคุมได้รับยาหลอก โดยมีจำนวนอาสาสมัครกลุ่มละ 70 คน ประเมินผลการรักษาโดยเปรียบเทียบคะแนนความปวด (VAS score) คะแนนคุณภาพชีวิต ปริมาณครีมและยาเม็ดบรรเทาปวดที่ใช้

ผลการศึกษา: การตรวจวัดหลังจาก 2 สัปดาห์ ในกลุ่มที่ได้รับไพลครีมมีค่า VAS score ลดลงเมื่อเทียบกับระยะเวลาเริ่มต้น อย่างไรก็ตาม เมื่อเปรียบเทียบทั้ง 2 กลุ่ม ค่า VAS score ไม่มีความแตกต่างกันทางสถิติ คุณภาพชีวิตระหว่าง 2 กลุ่ม ดีขึ้นหลังจากสัปดาห์ที่ 2 เมื่อเทียบกับเริ่มต้นศึกษา โดยค่าเฉลี่ยคะแนนคุณภาพชีวิตมากกว่า 50 แสดงถึงคุณภาพชีวิตที่ดีระหว่าง 2 กลุ่ม แต่ไม่พบความแตกต่างของคะแนนคุณภาพชีวิตตั้งแต่เริ่มต้นจนจบการศึกษาที่สัปดาห์ที่ 2 ไม่พบความแตกต่างทางสถิติในปริมาณครีมที่เหลือระหว่าง 2 กลุ่ม รวมถึงจำนวนยาเม็ดบรรเทาปวดที่ถูกใช้

สรุป: ครีมไพลมีประสิทธิภาพในการช่วยลดความปวดของอาการกล้ามเนื้อเคล็ด ข้อ ขอก ไม่แตกต่างจากยาหลอกในช่วงการวัด 2 สัปดาห์ แต่พบว่ามีแนวโน้มการลดลงของความปวดต่อเนื่องและเป็นการรักษาที่ไม่มีผลข้างเคียงจึงสามารถใช้ในการรักษาผู้ป่วยได้

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