ORIGINAL ARTICLE

A Double-Blind, Randomized Controlled Trial Comparing the Clinical Efficacy and Safety of Prasaprohyai Extract Capsules and Loratadine in Patients with Allergic Rhinitis

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Background: Prasaprohyai (PSP) is a traditional Thai remedy used to treat fever associated with cold symptoms, as listed in the National List of Essential Medicines of Thailand. Its ethanolic extract has been reported to have antiallergic effects in animal models.

Objective: To investigate the clinical efficacy and safety of PSP ethanolic extract in allergic rhinitis (AR) patients compared with loratadine.

Materials and Methods: A double-blind, randomized controlled trial comparison was used. The participants, including 162 patients with AR, were randomly divided into two groups using a pre-generated random assignment scheme enclosed in envelopes with 81 patients who were treated with 10 mg/day of loratadine, and 81 patients were treated with 300 mg/day of PSP capsule for six weeks. Efficacy was assessed through the level of nasal symptoms and the narrowest cross-sectional area (CSA) of the nasal cavity using acoustic rhinometry. In addition, safety was evaluated through blood biochemical tests conducted at weeks 0, 3, and 6.

Results: The results demonstrated that patients who received either the PSP ethanolic extract capsule or loratadine for six weeks showed continuous improvement in total nasal symptoms, including runny nose, nasal congestion, itchy nose, sneezing, and nasal cavity function. No significant differences were observed between the two groups. Additionally, blood biochemistry results for both groups remained within normal ranges, with no significant differences between them.

Conclusion: Both the PSP ethanolic extract capsule and loratadine were effective in the treatment of AR and showed no adverse events or safety concerns over the six-week administration period.

Trial registration: Thai Clinical Trials Registry, TCTR20231025003

Keywords: Prasaprohyai extract; Allergic rhinitis; Clinical trial; Loratadine

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The World Health Organization (WHO) declares chronic respiratory diseases as one of the four major health problems of mankind. Allergic rhinitis (AR) and chronic rhinosinusitis (CRS) affect more than 30% of the population worldwide. The socio-economic impact of chronic upper airway diseases was estimated in Europe at more than 150 billion Euros annually(1). This report suggests that AR and asthma will also increase in Thailand. A previous study supported this trend because the incidence of wheezing in Thai people increased fourfold, from 4.2% to 18.3%, and AR increased threefold, from 17.9% to 44.2%(2). The Ministry of Public Health of Thailand determined that the morbidity rate of respiratory diseases in 2023 was over one million people. AR as one of the disease codes in International Classification of Diseases, Tenth Revision, Thai modification (ICD-10-TM Code J30), was also reported in the same number of cases of respiratory disease(3).

Prasaprohyai (PSP) is traditionally used to

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Table 1. Plant ingredients in Prasaprohyai remedy formulation (for 100 g of powder drug)

Scientific name (Family)	Voucher specimen	Part of used	% by weight	Source
Amomum testaceum Ridl. (Zingiberaceae)	SKP206011101	Fruit	2.5	Chantaburi, Thailand
Anethum graveolens L. (Umbelliferae)	SKP199010701	Fruit	2.5	India
Angelica dahurica Benth. (Umbelliferae)	SKP199010401	Root	2.5	China
Angelica sinensis (Oliv.) Diels (Umbelliferae)	SKP199010901	Root	2.5	China
Artemisia annua L. (Compositae)	SKP051010101	All parts	2.5	China
Atractylodes lancea (Thunb.) DC. (Compositae)	SKP051011201	Rhizome	2.5	China
Cuminum cyminum L. (Umbelliferae)	SKP199030301	Fruit	2.5	India
Dracaena loureiri Gagnep. (Dracaenaceae)	SKP065041201	Heartwood	2.5	Chantaburi, Thailand
Foeniculum vulgare Mill. var. dulce (Mill.) Thell. (Umbelliferae)	SKP199062201	Fruit	2.5	India
Kaempferia galanga L. (Zingiberaceae)	SKP206110701	Rhizome	50	Sukhothai, Thailand
Lepidium sativum L. (Brassicaceae)	SKP057121901	Seed	2.5	India
Ligusticum sinense Olive. Cv. Chuanxiong (Umbelliferae)	SKP199121901	Rhizome	2.5	China
Mammea siamensis Kosterm. (Guttiferae)	SKP083131901	Flower	2.5	Ratchaburi, Thailand
Mesua ferrea L. (Guttiferae)	SKP08313060	Flower	2.5	Ratchaburi, Thailand
Mimusops elengi L. (Sapotaceae)	SKP171130501	Flower	2.5	Ratchaburi, Thailand
Myristica fragrans Houtt. (Myristicaceae)	SKP121130601	Nutmeg/aril	2.5	Chumphon, Thailand
Myristica fragrans Houtt. (Myristicaceae)	SKP121130601	Seed	2.5	Chumphon, Thailand
Myristica fragrans Houtt. (Myristicaceae)	SKP121130601	Heartwood	2.5	Chantaburi, Thailand
Nelumbo nucifera Gaertn. (Nelumboceae)	SKP125141401	Pollen	2.5	Nakorn Pathom, Thailand
Nigella sativa L. (Ranunculaceae)	SKP160141901	Seed	2.5	India
Syzygium aromaticum (L.) Merr. et Perry (Myrtaceae)	SKP123190101	Flower-bud	2.5	Chantaburi, Thailand

relieve fever associated with common cold symptoms in children, also known as Tan-Sang in the Thai language. It is in the National List of Essential Medicines of Thailand. The formulation comprises 21 medicinal plants, with the rhizome of *Kaempferia galanga* L. serving as the primary component, constituting 50% of the PSP formula (Table 1)[4]. PSP ethanolic extract has been studied for its anti-allergic properties[5]. Ethyl-p-methoxycinnamate (EPMC) and eugenol are the main active antiallergic ingredients as determined by high-performance liquid chromatography (HPLC)[6]. Eugenol has been shown to inhibit the systemic anaphylaxis induced by compound 48/80 at a dose of 10 µg/g body weight (BW) and showed a significant reduction in serum histamine levels[7]. PSP ethanolic extract had no acute or chronic toxicity when administered to rats[8].

The safety of the PSP ethanolic extract capsules was studied in healthy volunteers in a phase I clinical trial for six weeks. Twenty-four volunteers were divided into two groups by blocked randomization. Group 1 received 300 mg/day PSP ethanolic extract capsule before a meal. Group 2 received 600 mg/day of PSP ethanolic extract capsules before meals for eight weeks. The treatment was found to be safe, with no significant changes observed in blood biochemistry markers in either group of healthy volunteers[9].

A preliminary study of PSP ethanolic extract capsule was also conducted on the effectiveness and safety in AR patients for six weeks. Twenty AR patients took PSP ethanolic extract capsules 100 mg three times a day. The results demonstrated that the symptoms of AR were reduced within six weeks and there was no change in blood biochemistry markers, renal, and liver function[10].

Therefore, the objective of the present study was to compare the effects of PSP ethanolic extract capsules and loratadine on total nasal symptoms and the nasal cavity in AR patients. The safety of PSP ethanolic extract capsules was also investigated for treatment of AR patients.

Materials and Methods

Study design

The study design was a double-blind randomized controlled trial that examined the efficacy and safety of PSP ethanolic extract capsules for treatment in a large group of patients compared with loratadine. The present study was conducted in Thammasat University Hospital. The 162 patients were randomly assigned to the treatment and control groups using a pre-generated random assignment scheme, which was enclosed in envelopes. The present research was

approved by the Ethics Committee of the Faculty of Medicine, Thammasat University No.1 under protocol MTU-EC-ES-0-061/63 and registered online at Thai clinical trials.org under Ethical of TCTR ID: TCTR20231025003.

Plant material and preparation of PSP extract capsule

The preparation and quality control of herbal medicine from plants, including the components and proportions of the herbs are shown in Table 1. The quality control of herbal raw materials was studied using methods according to the Thai Herbal Pharmacopoeia 2019[11], which are tests for moisture content, total ash, and acid-soluble ash. The herbs were cleaned, dried, and ground into a coarse powder using a grinder. After weighing, the ingredients were mixed according to the formula and macerated in 95% ethanol for three days. The filtered residue was subsequently macerated in 95% ethanol for three days twice, and the filtrates were combined and evaporated using a vacuum rotary evaporator. The ethanolic extract of the PSP formula was mixed with the powdered excipients including lactose monohydrate, microcrystalline cellulose, and magnesium stearate, filled in size 0 capsules, 500 mg per capsule, ensuring the extract content was 100 mg per capsule. The capsules were then packed in aluminum blisters to protect them from light and moisture.

The quality of PSP capsule was assessed based on the criteria of the Thai herbal pharmacopoeia[11] regarding the physical characteristics of the drug, such as weight variation, moisture content, and capsule disintegration. The PSP extract capsules passed microbial and heavy metals contamination testing at the laboratory of the Center of Excellence for Pharmaceutical Research, Faculty of Pharmaceutical Sciences, Thammasat University. The active ingredients, EPMC and eugenol, were analyzed using HPLC[5]. The biological activity was evaluated based on the extract's anti-allergic potential, using an inhibitory assay measuring β-hexosaminidase release from RBL-2H3 cells. The extract with acceptable antiallergic activity had an IC_{50} value less than 30 µg/mL.

The PSP ethanolic extract capsule, containing 100 mg of PSP per capsule, passed quality control and stability testing. The standard treatment was 10 mg loratadine per capsule. Both interventions were filled in same size and color as the capsule, sealed in aluminum blisters, and placed in an opaque container to ensure blinding to the participants. The placebo used in the present study consisted of lactose-filled capsules, designed to match the color of the PSP capsules to ensure double-blinding for both researchers and participants.

Participants

The inclusion criteria of the present study were as follows, patients with AR, male or female aged 20 to 64 years. The total nasal symptom score (TNSS) indicated moderate to moderately severe AR, with total scores of 5 points or higher. Laboratory tests showed normal hematological values as well as normal kidney and liver function. The exclusion criteria were as follows, the subjects who took anticoagulant and antiplatelet drugs and those with confirmed allergies to drugs or history of severe side effects from loratadine. Patients with history of congenital diseases such as tuberculosis, rhinitis, kidney disease, heart disease, liver disease, epilepsy, severe asthma, and high blood pressure were also excluded. In addition, subjects who were immunocompromised or HIV-positive were excluded. The sample size was calculated using the TNSS from a pilot study with 15% dropout. The sample size (n) for each group was 81 participants, thus a total of 162 participants.

Interventions

The subjects were divided into two groups, an experimental group, and a control group. The experimental group received 100 mg PSP extract per capsule after meals three times daily. The control group received loratadine 10 mg per capsule once a day after breakfast and a placebo capsule after lunch and dinner. Both groups received treatment drugs for six weeks. Capsules containing PSP extract, loratadine and placebo were identical in appearance, size, and color to prevent any unintentional bias. In addition, randomization codes were kept confidential and were only revealed after data analysis was completed.

The time required for subjects to report all outcomes was six weeks. The complete blood count, renal function tests, liver function tests, and urine samples were also assessed and collected before the first exposure to the database. Follow-up assessments for all patients were conducted at three and six weeks. Outcome measures included evaluation of nasal symptoms and the degree of nasal congestion, which were assessed using acoustic rhinometry (ARM) by measuring the narrowest cross-sectional area (CSA) of the nasal cavity.

Statistical analysis

Descriptive statistics were used to summarize the characteristics of the volunteers. The results are presented as number, percentage for qualitative data and mean, standard deviation (SD) or median, interquartile range for quantitative data. Inferential statistics, including chi-square test, independent sample t-test, and Mann-Whitney U test, were used for between-group comparisons, while the paired t-test and Wilcoxon signed-rank test were applied for within-group comparisons. Statistical significance was defined as a p-value less than 0.05 ($p<0.05$). IBM SPSS Statistics for Windows, version 29.0 (IBM Corp., Armonk, NY, USA) was used for data analysis.

Results

The study results consisted of three parts. The first part was quality control of the PSP extract capsule. The second part was the efficacy of drug to subjects, which was evaluated by TNSS, the CSA of the nasal cavity measured with ARM. The third part focused on safety, evaluated through blood biochemistry tests assessing renal and liver function, complete blood counts, and monitoring adverse events.

Quality control of plant material and PSP extract capsules

The PSP extract had a percentage yield of 5.05% w/w. Analysis of the PSP capsules revealed no contamination with heavy metals such as lead, arsenic, or cadmium, and no bacterial contamination, in accordance with the Thai Herbal Pharmacopoeia criteria[11]. The chemical content in PSP capsule showed EPMC and eugenol as 227.1 mg/g and 52.9 mg/g, respectively, and anti-allergic activity as 16.27±1.68 µg/mL. The PSP capsule passed following Pharmacopoeia on weight variation, disintegration time, and moisture content[11].

Efficacy of PSP extract capsule

General information on subjects:

A total of 168 patients with AR had passed the history taking and physical examination, six were excluded from the study, and 162 met the study criteria. The 162 patients were randomized into two intervention groups with 81 patients receiving PSP extract capsules at a dose of 300 mg/day, while the other 81 patients received loratadine at a dose of 10 mg/day. All volunteers began participating in the clinical trial at week 0. Afterwards, 12 volunteers in the PSP extract group and 11 volunteers in the loratadine group left the trial in week 3. Sixty-nine patients in the PSP extract group and 70 patients in the loratadine group completed the follow-up and were included in the final analysis (Figure 1).

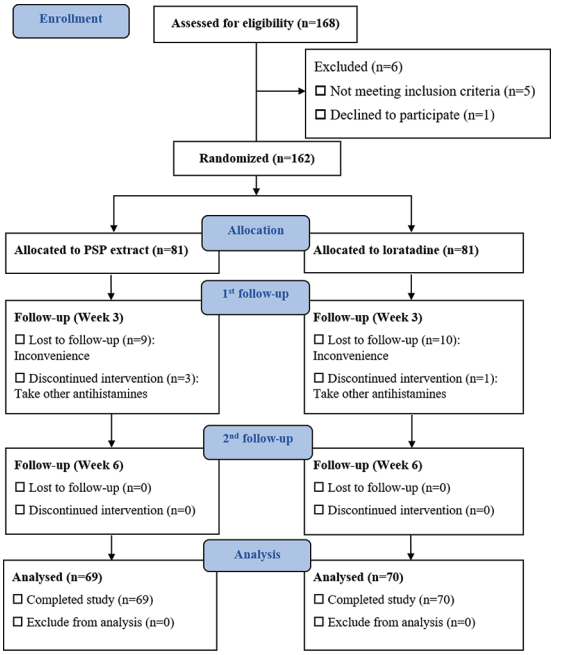

Figure 1. Flow chart of the study design.

The initial data of the volunteers participating in the trial in both groups were average age, aspartate transaminase (AST), alanine transaminase (ALT), and red blood cell (RBC) counts. The mean age of the PSP extract group was greater than the loratadine group. However, there was no statistical difference in most of the baseline characteristics, including gender, total nasal symptoms, ARM, biochemistry, and hematology (Table 2).

Total nasal symptom score:

Taking PSP extract and loratadine for six weeks continuously improved symptoms of total nasal symptoms, runny nose, nasal congestion, itchy nose, and sneezing. There was no difference between the groups taking loratadine and PSP extract. When comparing within-group, significant relief of total nasal symptoms, runny nose, nasal congestion, itchy nose, and sneezing was evident (Table 3).

Measuring the CSA of the nasal cavity with ARM:

When comparing between groups, the two groups differed in the right minimal cross-sectional area (MCA_R), right volume (Vol_R), and total volume (Total_Vol). Furthermore, within-group comparisons revealed that, after three weeks, volunteers who received the PSP extract showed an increasing trend

Table 2. General information of subject volunteer participants receiving PSP extract and loratadine

Data	PSP extract 300 mg/day (n=69)	Loratadine 10 mg/day (n=70)	p-value[T]
General information about subject volunteer participant			
Age (years); mean [SD]	34.67 [13.14]	29.57 [11.59]	0.017*
Sex (male); n (%)	18 (26.1)	18 (25.7)	0.960[C]
Blood circulation; mean [SD]			
Heart rate (/minutes)	71.75 [7.79]	72.32 [7.59]	0.115
Systolic blood pressure (mmHg)	112.25 [12.36]	109.99 [13.05]	0.298
Diastolic blood pressure (mmHg)	69.96 [9.44]	72.32 [7.59]	0.469
Total nasal symptom score (TNSS)			
Total nasal symptoms; median (Q1, Q3)	6 (5, 7)	6 (5, 9)	0.211[M]
Runny nose; mean [SD]	1.65 [0.80]	1.73 [0.88]	0.594
Itchy nose; mean [SD]	1.49 [0.78]	1.56 [0.90]	0.652
Nasal congestion; median (Q1, Q3)	2 (1, 2)	2 (1, 3)	0.205[M]
Sneezing; mean [SD]	1.49 [0.83]	1.73 [0.82]	0.094
Acoustic rhinometry; mean [SD]			
MCA_R	0.53 [0.53]	0.42 [0.22]	0.103
MCA_L	0.45 [0.23]	0.49 [0.23]	0.392
Total MCA	0.98 [0.59]	0.91 [0.39]	0.367
Volume_R	5.39 [2.51]	4.83 [2.12]	0.149
Volume_L	5.47 [2.41]	5.30 [2.24]	0.669
Total volume	10.86 [3.82]	10.14 [3.91]	0.271
Dis_R	1.64 [0.37]	1.60 [0.29]	0.295
Dis_L	1.59 [0.23]	1.58 [0.31]	0.813
Biochemistry; mean [SD]			
BUN (mg/dL)	11.90 [2.94]	10.87 [2.87]	0.039*
Creatinine (mg/dL)	0.75 [0.16]	0.73 [0.16]	0.633
Total bilirubin (mg/dL)	0.58 [0.25]	0.58 [0.25]	0.660
Direct bilirubin (mg/dL)	0.18 [0.09]	0.17 [0.08]	0.241
AST (U/L)	24.46 [9.86]	19.51 [5.54]	0.381
ALT (U/L)	23.23 [14.99]	18.69 [8.80]	0.914
ALP (U/L)	64.77 [18.16]	62.70 [19.10]	0.568
Hematology; mean [SD]			
WBC ($10^3/cm^3$)	6.34 [1.65]	6.49 [1.53]	0.579
RBC ($\times 10^6/cm^3$)	4.95 [0.64]	4.74 [0.59]	0.039*
Hb (g/dL)	13.04 [1.69]	12.86 [1.42]	0.490
Platelet (10^3/cu.mm)	286.07 [61.99]	296.47 [64.72]	0.335

PSP=Prasaprohyai; MCA=minimal cross-sectional area; Dis=distance; R=right; L=left; BUN=blood urea nitrogen; AST=aspartate transaminase; ALT=alanine transaminase; ALP=alkaline phosphatase; WBC=white blood cell; RBC=red blood cell; Hb=hemoglobin; SD=standard deviation
(T) Independent samples t-test, (M) Mann-Whitney U test, (C) Chi-square test, * Statistically significant ($p<0.05$)

in the left-sided minimal cross-sectional area (MCA), increasing from 0.45 to 0.54 cm^2 with left volume and total volume greater than before taking the drug. However, the nasal cavities in the loratadine group did not change (Table 4).

Safety of PSP extract capsule

Renal function tests:

Renal function tests in volunteers taking PSP extract and loratadine showed no differences between the groups.

When comparing within-group, the mean values of the volunteers in both groups did not exceed the reference standard, and blood urea nitrogen (BUN) values did not show significant changes compared to baseline. However, a decrease in BUN levels was observed in the PSP extract group at the third week. It could be concluded that volunteers who received PSP extract and loratadine continuously for six weeks did not exhibit kidney toxicity according to measured blood biochemistry (Table 5).

Table 3. A comparative assessment of PSP extract and loratadine group with total nasal symptom score (TNSS)

Data	Follow-up	Treatment; mean (SD)		p-value[B]
		PSP extract[W] (n=69)	Loratadine[W] (n=70)	
Total TNSS score (score 0 to 12)	Week 0	6.43 (1.87)	6.91 (2.58)	0.211
	Week 3	4.26 (1.96)*	4.77 (2.09)*	0.139
	Week 6	4.03 (2.34)*	3.76 (2.12)*	0.473
Runny nose (score 0 to 3)	Week 0	1.65 (0.80)	1.73 (0.88)	0.594
	Week 3	1.10 (0.71)*	1.27 (0.74)*	0.170
	Week 6	1.07 (0.77)*	1.00 (0.70)*	0.564
Itchy nose (score 0 to 3)	Week 0	1.49 (0.78)	1.56 (0.90)	0.652
	Week 3	0.99 (0.72)*	1.03 (0.79)*	0.739
	Week 6	0.93 (0.80)*	0.77 (0.64)*	0.203
Nasal congestion (score 0 to 3)	Week 0	1.83 (0.68)	1.99 (0.79)	0.205
	Week 3	1.25 (0.77)*	1.31 (0.71)*	0.592
	Week 6	1.12 (0.80)*	1.07 (0.73)*	0.731
Sneezing (score 0 to 3)	Week 0	1.49 (0.83)	1.73 (0.82)	0.094
	Week 3	1.03 (0.80)*	1.16 (0.69)*	0.316
	Week 6	0.91 (0.74)*	0.93 (0.71)*	0.907

PSP=Prasaprohyai; SD=standard deviation

(B) Comparison between-group: Independent samples t-test, (W) Comparison within-group from week 0: Paired t-test, * Statistically significant ($p<0.05$)

Table 4. A comparative assessment of PSP extract and loratadine group with acoustic rhinometry

Parameter	Follow-up	Treatment; mean (SD)		p-value[B]
		PSP extract[W] (n=69)	Loratadine[W] (n=70)	
MCA_R (cm^2)	Week 0	0.53 (0.52)	0.42 (0.22)	0.103
	Week 3	0.56 (0.39)	0.43 (0.24)	0.036*
	Week 6	0.52 (0.37)	0.44 (0.25)	0.118
MCA_L (cm^2)	Week 0	0.45 (0.23)	0.49 (0.23)	0.392
	Week 3	0.54 (0.25)*	0.56 (0.44)	0.713
	Week 6	0.49 (0.22)	0.47 (0.24)	0.679
Total MCA (cm^2)	Week 0	0.98 (0.59)	0.91 (0.39)	0.367
	Week 3	1.09 (0.50)	0.99 (0.56)	0.294
	Week 6	1.01 (0.51)	0.91 (0.42)	0.201
Right volume	Week 0	5.39 (2.51)	4.83 (2.12)	0.149
	Week 3	5.88 (2.51)	5.05 (2.21)	0.042*
	Week 6	5.68 (2.15)	5.14 (2.28)	0.148
Left volume	Week 0	5.47 (2.41)	5.30 (2.24)	0.669
	Week 3	6.33 (2.57)*	5.78 (2.37)	0.186
	Week 6	6.04 (2.89)	5.46 (2.29)	0.190
Total volume	Week 0	10.86 (3.82)	10.14 (3.91)	0.271
	Week 3	12.21 (4.36)*	10.83 (3.84)	0.049*
	Week 6	11.77 (4.06)	10.60 (4.00)	0.089
Dis_R (cm)	Week 0	1.64 (0.37)	1.58 (0.31)	0.295
	Week 3	1.58 (0.27)	1.58 (0.31)	0.968
	Week 6	1.63 (0.31)	1.55 (0.28)	0.094
Dis_L (cm)	Week 0	1.59 (0.23)	1.60 (0.29)	0.813
	Week 3	1.59 (0.25)	1.56 (0.40)	0.547
	Week 6	1.58 (0.26)	1.57 (0.34)	0.764

PSP=Prasaprohyai; MCA=minimal cross-sectional area; Dis=distance; R=right; L=left; SD=standard deviation

(B) Comparison between-group: Independent samples t-test, (W) Comparison within-group from week 0: Paired t-test, * Statistically significant ($p<0.05$)

Table 5. The comparison of the renal function, liver function and complete blood count tests in patients receiving PSP extract and the loratadine group

Laboratory test	Follow-up	Treatment		p-value
		PSP extract (n=69)	Loratadine (n=70)	
Renal function tests; mean (SD)				
BUN (mg/dL) (ref. value=7.0 to 18.0)	Week 0	11.90 (2.94)^{W1}	10.87 (2.87)^{W1}	0.039^{B1}*
	Week 3	11.39 (2.96)^{W1}	11.55 (3.10)^{W1}	0.756^{B1}
	Week 6	11.61 (3.37)^{W1}	11.28 (2.92)^{W1}	0.531^{B1}
Creatinine (mg/dL) (ref. value=0.67 to 1.17)	Week 0	0.75 (0.16)^{W1}	0.73 (0.16)^{W1}	0.633^{B1}
	Week 3	0.75 (0.16)^{W1}	0.74 (0.16)^{W1}	0.722^{B1}
	Week 6	0.75 (0.16)^{W1}	0.73 (0.16)^{W1}	0.436^{B1}
Liver function tests; mean (SD)				
AST (U/L) (ref. value=15 to 37)	Week 0	24.46 (9.86)^{W1}	19.51 (5.57)^{W1}	0.000^{B1}*
	Week 3	21.80 (6.76)^{W1}*	20.67 (6.48)^{W1}	0.318^{B1}
	Week 6	21.25 (8.22)^{W1}*	20.34 (5.76)^{W1}	0.454^{B1}
ALT (U/L) (ref. value=16 to 63)	Week 0	23.23 (14.99)^{W1}	18.69 (8.80)^{W1}	0.031^{B1}*
	Week 3	22.48 (13.37)^{W1}	20.35 (12.62)^{W1}	0.338^{B1}
	Week 6	22.29 (14.55)^{W1}	20.46 (11.40)^{W1}	0.409^{B1}
Direct bilirubin (0.0 to 0.2 mg/dL)	Week 0	0.18 (0.09)^{W1}	0.17 (0.08)^{W1}	0.568^{B1}
	Week 3	0.19 (0.10)^{W1}	0.16 (0.08)^{W1}	0.157^{B1}
	Week 6	0.17 (0.08)^{W1}	0.15 (0.07)^{W1}*	0.080^{B1}
Total alkaline phosphatase (46 to 116 U/L)	Week 0	64.77 (18.17)^{W1}	62.70 (19.10)^{W1}	0.514^{B1}
	Week 3	65.83 (20.34)^{W1}	62.29 (19.33)^{W1}	0.295^{B1}
	Week 6	66.56 (19.81)^{W1}	61.76 (19.23)^{W1}	0.151^{B1}
Complete blood count test; median (Q1, Q3)				
WBC (4 to 11 K/mm^3)	Week 0	6.21 (5.28, 7.09)^{W2}	6.38 (5.48, 7.34)^{W2}	0.579^{B2}
	Week 3	6.21 (5.32, 7.02)^{W2}	6.28 (5.32, 7.23)^{W2}	0.363^{B2}
	Week 6	6.27 (5.40, 7.38)^{W2}	6.12 (5.27, 7.48)^{W2}	0.982^{B2}
RBC (4.50 to 6.00 $\times 10^6$/mm^3)	Week 0	4.95 (4.47, 5.18)^{W2}	4.65 (4.33, 5.12)^{W2}	0.039^{B2}*
	Week 3	4.79 (4.54, 5.18)^{W2}*	4.69 (4.33, 5.02)^{W2}	0.151^{B2}
	Week 6	4.83 (4.48, 5.21)^{W}2*	4.64 (4.39, 5.08)^{W2}	0.086^{B2}
Hb (14.0 to 18.0 g/dL)	Week 0	13.20 (12.40, 13.90)^{W2}	12.85 (12.00, 13.50)^{W2}	0.490^{B2}
	Week 3	13.10 (12.20, 13.80)^{W2}	12.60 (12.10, 13.70)^{W2}	0.693^{B2}
	Week 6	12.90 (12.40, 13.80)^{W2}*	12.70 (12.00, 13.5)^{W2}	0.802^{B2}
Platelets (150 to 400 K/mm^3)	Week 0	287.00 (245.00, 321.00)^{W2}	288.50 (252.00, 327.00)^{W2}	0.335^{B2}
	Week 3	278.00 (247.00, 324.00)^{W2}	280.50 (246.00, 322.00)^{W2}	0.661^{B2}
	Week 6	285.00 (251, 314)^{W2}	286.00 (240.00, 332.00)^{W2}	0.507^{B2}

PSP=Prasaprohyai; BUN=blood urea nitrogen; AST=aspartate transaminase; ALT=alanine transaminase; WBC=white blood cell; RBC=red blood cell; Hb=hemoglobin; SD=standard deviation

(B1) Comparison between-group: Independent samples t-test, (B2) Comparison between-group: Mann Whitney U test, (W1) Comparison within-group from week 0: Paired t-test, (W2) Comparison within-group from week 0: Wilcoxon signed-rank test, * Statistically significant ($p<0.05$)

Liver function tests:

Liver function tests in volunteers taking PSP extract had a higher mean baseline AST and ALT than the loratadine group. There was no difference between the values obtained in both groups in the third and sixth week.

The comparative within-group AST value of the PSP group at the third and sixth weeks decreased when compared to day 0. While the mean ALT of the PSP extract group showed no significant differences compared with day 0. The mean AST and ALT values in volunteers receiving loratadine were not significantly different from baseline before intervention.

Therefore, it can be concluded that volunteers who received PSP extract and loratadine for six consecutive weeks did not experience discernible liver toxicity (Table 5).

Complete blood count test:

There was no difference between the PSP and

the loratadine groups in white blood cell (WBC), hemoglobin (Hb), and platelets, but a difference in RBC.

When compared within groups, it was found that during the six weeks of taking the drug, the mean RBC and hematocrit (Hct) at the third and sixth weeks were lower than the pre-treatment means. Furthermore, mean corpuscular hemoglobin (MCH) and basophil values in week three increased compared to pre-treatment. Moreover, mean monocyte and Hb were decreased in week six compared to pre-treatment.

In the loratadine group, the mean corpuscular volume (MCV) and red cell distribution width (RDW) were decreased in week six compared to pre-treatment, but the mean corpuscular hemoglobin concentration (MCHC) increased in week six compared to pre-treatment (Table 5).

Discussion

The present study aimed to investigate the effect of PSP extract capsules versus loratadine on total nasal symptoms and the nasal cavities in patients with AR. This clinical research reported the TNSS, the CSA of the nasal cavities with ARM, the results of renal function tests, liver function tests, and blood count tests.

TNSS scores showed significant relief of total nasal symptoms, runny nose, nasal congestion, itchy nose, and sneezing in both groups. The results are consistent with previous research on the pharmacological activities of PSP remedy, including anti-allergic, anti-inflammatory, antioxidant, antipyretic, antibacterial, and analgesic activities[5,10,12,13]. AR is characterized by a chronic inflammation of the nasal mucosa[1]. Therefore, PSP remedy has been investigated for anti-inflammatory and antiallergic activity to treat AR and its symptoms, such as a runny and itchy nose and nasal congestion. A previous study of PSP drug (95% EtOH) demonstrated efficacy in treating AR. After taking PSP extract for six weeks, subjects had a significantly reduced nasal symptom score from 6.40±1.00 in week 0 to 4.15±1.98 in week 6[10].

AR scores, the two groups differed in the MCA_R, Vol_R, and Total_Vol. A review of the literature found that, according to Tantilipikorn et al.[14] the MCA on the measured by ARM in Thai individuals was 0.61±0.60 cm^2 before nasal spray. After nebulization with a 3% ephedrine solution to relieve nasal congestion caused by mucosal swelling, an increase in MCA was 0.64±0.14 cm^2. The values obtained before nebulization showed that the MCA tended to increase, while the distance from the anterior opening of the nose to the point of the MCA, which represents the depth of the nasal cavity measured by ARM, tended to decrease after nebulization[14].

It was found that the PSP remedy also had the same effect as determined by ARM on nasal congestion in the present research. Therefore, people who take PSP extract would also likely have reduced nasal congestion caused by swelling of the nasal mucosa. The MCA values in the group that took PSP extract were statistically significantly wider than loratadine group after three weeks of treatment, suggesting a decrease in nasal obstruction and congestion. The PSP remedy extract inhibited nitric oxide (NO) with an IC_{50} value of 18.40±0.43 µg/mL, showing a significant anti-inflammatory effect[12]. In contrast, there was no significant difference in the MCA values in the loratadine group, consistent with a literature review of antihistamines. It was established that antihistamines can help reduce symptoms of sneezing, runny nose, nasal itching, watery eyes, and itchy eyes, but have less effect on nasal congestion[15].

Renal and liver function tests indicated that volunteers received either PSP extract or loratadine continuously for six weeks did not exhibit any signs of kidney or liver toxicity. All participants maintained normal liver and renal function throughout the Phase II clinical study of the PSP remedy[9].

In blood count tests, there were no differences between the groups who had taken PSP extract and loratadine in WBC, Hb, and platelets but only between-group differences in RBC. However, the value of such changes has no apparent clinical effect. Relevant studies have described changes in hematological effects in chronic rhinitis. No correlation was found between a positive skin prick test and hematological parameters, including changes in RBC and Hb levels, in patients with AR. It is the effect that can be found in illnesses not caused by allergies. Moreover, decreased WBC was found in allergic and non-allergic people with prolonged symptoms[15,16].

Conclusion

The clinical trial results demonstrate that the PSP extract capsules have a therapeutic effect equivalent to loratadine. PSP extract capsules in the present study were shown to be safe, with no acute or chronic toxic effects observed in blood, liver, or kidney biomarkers. These findings further support the efficacy and safety

of PSP extract for use in patients with AR.

What is already known about this topic?

PSP was listed in the Thai national health list. It is known for its ability to relieve fever and cold symptoms. In addition, PSP has been reported to have good anti-inflammatory and anti-allergic effects. Many studies suggested that PSP has a therapeutic effect as an anti-allergic treatment and is safe to use.

What does this study add?

This phase III clinical trial confirms PSP has a therapeutic effect equivalent to loratadine in treating AR. The study supports PSP as a safe, natural treatment option for AR as reflected in data on safety, efficacy, and quality of life.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

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