Phase II Clinical Trial of Ayurved Siriraj Wattana Recipe for Symptomatic Relief in Patients with Osteoarthritis of the Knee

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Background: *Osteoarthritis of the knee is one of the most common public health problems in Thailand and throughout the world. It causes disability, with pain and loss of function. Nonsteroidal anti-inflammatory drugs (NSAIDs) are the most common treatment modality to relieve pain for OA, but can cause undesirable adverse effects. Effective and safer alternative treatments for OA are urgently needed. Among the many kinds, Ayurved Siriraj Wattana Recipe has been widely used in humans for a long time. The components of the recipe probably were related with many systems of the body such as the immune system and the gastrointestinal system and it may have anti-inflammatory activity as well as anti-oxidative capacity.*
Objective: *Determine the efficacy of Ayurved Siriraj Wattana Recipe for knee osteoarthritis in a randomized, open-label, diclofenac-controlled trial for 12 weeks. The trial has been approved from Siriraj Institutional Review Board (SIRB), Faculty of Medicine, Siriraj Hospital, Mahidol University.*
Material and Method: *Analyze the 12-item Oxford, defined as 5-point Likert scales of pain and functional activity. The secondary assessment included 10-cm VAS pain assessment tool as well as, patients' and physician's global efficacy assessment.*
Results: *"12-Item Oxford" revealed that patients had mild problems in terms of function and pain with an average function score observed between groups ($p = 0.6$). The average pain score at 12 weeks' follow-up was not significantly different in the Wattana group compared with the diclofenac group ($p = 0.3$). Responses with no differences included the mean 10-cm VAS that assessed pain at 12 weeks' follow-up in both groups. There were no significant differences in the patients' and physician's global efficacy assessment with patients in both groups. There were no differences in the frequent of adverse events between groups. In addition, there were no significant differences in the patients' and physician's global safety assessment between groups.*
Conclusion: *The present, diclofenac-controlled trial concludes that Ayurved Siriraj Wattana Recipe treatment could be an effective treatment of pain in knee OA at 12 weeks.*

Keywords*: Ayurved Siriraj Wattana Recipe, Diclofenac, Osteoarthritis of the knee, Oxford knee score*

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Osteoarthritis of the knee is one of the most common public health problems in Thailand and throughout the world. It causes disability, with pain and loss of function. OA management should be a multidisciplinary approach, as it typically affects patients with OA with multiple comorbidities. Among treatment modalities, nonsteroidal anti-inflammatory drugs (NSAIDs) are the most common treatment modality to relieve pain for OA, but most of them can cause undesirable adverse effects. The effective and safer alternative treatments for OA are urgently needed. Recently, Thai herbs have been used widely as medical plants for drugs[1]. Among the many kinds, the Ayurved Siriraj Wattana Recipe has been perfectly well-known by certain Thai herb practitioners. Especially, it effectively treats weak decaying knees[2]. It is a stimulant as well.

Ayurved Siriraj Wattana Recipe has been served to patients at Ayurved School for a long time, the Thai Institution of Medicinal Applied Science since B.E. 2546. This recipe is composed of 15 kinds of herbs, each of which contains a variety of

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phyto-chemical compounds. They are namely, *Piper nigrum*, *Boesenbergia pandurata*, *Tinospora cordifolia*, *Terminalia chebula, Cladogynos orientalis, Ferula assafoetida, Saussurea lappa, Cyperus rotundus, Derris scandens*, *Anamirta cocculus, Drypetes roxburghii*, *Cinnamomum siamense*, *Aegle marmelos*, *Conioselinum univitatum* and *Cryptolepis buchannani*. However, the recipe has been widely used for many decades and there are no reports of danger. The World Health Organization advises continued studying and research on the human body[3]. Thai herbs practitioner are still concerned that if serving of 900 mg/day are given, this is safe and there are no side effects in treatment whatever. The aim of the present study was therefore to determine the effect of Ayurved Siriraj Wattana Recipe for symptomatic relief in patients with osteoarthritis of the knee.

Material and Method

Preparation of Ayurved Siriraj Wattana Recipe

Dose 300 mg prepared by unit of pharmaceuticals of Institution of Thai Traditional Medicine Applied Science, with quality controlled, signed, together with Fingerprint by Thin Layer Chromatography (TLC) and Ultra Performance Liquid chromatography (UPLC). Pills for this experiment were stored and preserved in a room temperature at 25°C dry and clean[4].

Patients

Male and female patients had age over 50 years old. OA was diagnosed in patients with radiographs, and assessed by the Kellgren et al[5] grading system for severity of arthritis[6]. Patients had visual analogue scale score during the most painful knee movement over than 4 cm after use of concomitant prohibited medication other than acetaminophen. Patients with the following unsuitable condition in study are excluded: A history of underlying inflammatory arthropathy or severe rheumatoid arthritis, recent injury in the area affected by OA of the knee and expectation of surgery in the future. Patients with secondary knee OA, those who received intra-articular treatment of the signal joint with any product.

Study design

This randomized, open-label, NSAIDs-controlled trial has been approved from the Siriraj Institutional Review Board (SIRB), Faculty of Medicine, Siriraj Hospital, Mahidol University. Sixty selected patients with symptoms of mild to moderate OA were recruited into the study. Each patient was randomly assigned to a treatment group using computer-generated blocks of four (Excel 5.0). Treatment allocation depended only on the time sequence in which patients entered the present study, thus minimizing selection bias. The patients were divided into two groups of 30 persons each: Ayurved Siriraj Wattana Recipe group (900 mg/day) and Diclofenac (25 mg) three times per day.

Questionnaires

Disease specific questionnaires

Oxford 12 item knee score (Oxford-12)[7]

The Oxford 12 is a questionnaire asked specifically for the knee with 12 questions. Each question has a Likert-box response key from 1 to 5. A low score indicates a better state of health. These 12 items were classified into two main scales: function and pain. The function scale comprised seven questions i.e., 2, 3, 6, 7, 10, 11, and 12 while pain scale comprised five questions i.e., 1, 4, 5, 8, and 9. Therefore, function score, pain score, and total score were in the range of 1 to 35, 1 to 25, and 1to 60 respectively. It is a short, simple, and validated questionnaire to assess the outcomes, as judged by the patient[8]. Secondary efficacy variables included 10-cm VAS that assessed pain during the most painful knee movement[9], global efficacy assessment by the patient, and the physician using a 4-point scale (''How well do you feel the treatment has worked thus far?'' not effective; slightly effective; moderately effective; very effective). The physician's assessed the patients' functional disability at baseline and on each follow-up visit (week 2, 4, 8, and 12).

Safety parameters

Hematological and chemical chemistry evaluations

For assessment of safety of Ayurved Siriraj Wattana Recipe, several parameters such as complete blood count (CBC), Fasting Blood Sugar (FBS), liver function (AST, ALT), and renal function (BUN, Creatinine) were evaluated in serum and whole blood of all patients at the beginning and the end of the present study.

Physical examination

Vital signs (Body temperature, Pulse rate, Blood pressure) were also recorded at the baseline and at every visit.

Adverse drug reaction

Adverse events (AEs) or adverse drug reaction were recorded at each visit and assessed by the investigator.

Patients' and physician's global tolerability assessment

Patients were asked to assess the tolerability of the present study treatment globally (''How well did you tolerate the treatment?'') at each visit after baseline using a 5-point Likert scale (nil; poor; moderate; good; very good). The investigators also provided a judgment on tolerability (''How well do you think the patient tolerated the treatment?'') using the same scale.

Statistical consideration

Sample size estimation

A sample of 50 patients would be sufficient to test a large (r = 0.80) but statistically significant difference between groups at week 12 from mean difference of Oxford-12 score at 2-sided type I of 0.05 and power of 80%[8,10]. Estimating that 20% drop-out of sampled patients were five persons, therefore 60 persons are required in the study.

Data analysis

The data were analyzed using SPSS for Windows, version 13. Data were presented as mean $\pm$ SD, n (%). Comparative analysis was focused at the end of treatment (week 12). To determine the effectiveness of the intervention, two-factor repeated-measures analysis of variance and paired t-test were used when appropriate. Chi-square test was used to determine the similarity of patients' and physician's global assessment between the groups. All tests were two-sided, and had a significant level at a p-value < 0.05.

Statistical analyses to test the superiority were based on the intention-to-treat (ITT) population. Intention-to-treat analysis was used because of sample loss. This is generally interpreted as including all patients, regardless of the actual satisfaction of the entry criteria, actual receipt of the treatment, and subsequent withdrawal or deviation from the protocol. Individuals who had withdrawn from the research should be kept track of in order to keep the data loss at minimum.

Results

Subject demography and clinical characteristics

Sixty patients were enrolled into the present study. They were randomized to 900 mg/day Ayurved Siriraj Wattana Recipe or 75 mg/day diclofenac groups. Finally, 27 patients (90%) in the Ayurved Siriraj Wattana Recipe group and 24 patients (80%) in the diclofenac group completed the study. Nine patients withdrew before the end of the present study including three patients in 900 mg/day the Ayurved Siriraj Wattana Recipe group (1 patient: adverse event, 2 patients: lost to follow-up) and six patients in the 75 mg/day diclofenac group (1 patient: lack of efficacy, 2 patients: adverse event and 3 patients: lost to follow-up). Most of the subjects were females (83%-90%) with mean age of 63 years and body-mass index of 24 kg/m^2. About half of them had grade II and grade III K&L criteria confirmed by both Knees AP lateral/skyline X-ray. The mean 12-Item Oxford Knee pain score were 14.3 and 14.5, mean 12-Item Oxford Knee function score were 18 and 18.3 in the Ayurved Siriraj Wattana Recipe and the diclofenac groups, respectively. The mean VAS 10-cm that assessed pain (VAS assessed pain) of both groups were 6.6-6.7 cm. Treatment groups were homogeneous with respect to demographics, vital signs, baseline disease characteristics and baseline outcome measures (that is, 12-item Oxford knee score; pain, function score and VAS assessed pain) (Table 1). Although there are some differences in baseline characteristics of sex, age, body-mass index, clinical baseline characteristic, and baseline outcome measures, those are statistically not significant ($p > 0.05$).

Oxford-12

The mean 12-item Oxford knee score; pain score, function score between two groups at week 12 (Intention-to-treat analysis) are presented in Table 2. 12-Items Oxford Knee score; pain score for 900 mg thrice daily Ayurved Siriraj Wattana Recipe were not significantly different from those for diclofenac 75 mg thrice daily at 2, 4, 8, and 12 weeks ($p > 0.05$). No significant differences were noted between the Ayurved Siriraj Wattana Recipe treatment and diclofenac in terms of improvement in 12-Items Oxford Knee score; function score.

Secondary efficacy variables - visual analogue scale (VAS) assessed pain

The dosages of 900 mg/day Ayurved Siriraj Wattana Recipe and 75 mg/day diclofenac were associated with a reduction in pain, as assessed by the VAS pain scale. The mean changes from baseline of Visual Analogue Scale that assessed pain in Ayurved Siriraj Wattana Recipe and the diclofenac groups were -2.26 and -2.16 cm. respectively with the mean difference

Table 1. Demographic data and baseline characteristics of patients

Patients baseline characteristics	Wattana 900 mg/day (n = 30)	Diclofenac 75 mg/day (n = 30)
Sex (male/female; n)	5/25	3/27
Mean (SD) age, y)	64.7 (8.7)	60.8 (7.1)
Age range (years)	50-81	50-75
Mean (SD) body mass index, kg/m^2	23.6 (2.5)	24.1 (4.6)
Mean (SD) pulse, min	80 (11.3)	84.4 (1.8)
Mean (SD) systolic blood pressure, mm Hg	129.5 (14)	132.2 (12.1)
Mean (SD) diastolic blood pressure, mm Hg	72.5 (7.7)	77.1 (8.1)
Kellgren-Lawrence grade, No.		
I	-	-
II	18	19
III	12	11
IV	-	-
Mean (SD) visual analog score, cm	6.57 (1.5)	6.67 (1.5)
12-items Oxford knee scores		
Mean (SD) pain scores	14.3 (2.85)	14.46 (3.92)
Mean (SD) function scores	18.0 (5.11)	18.26 (5.98)

Values are expressed as mean (standard deviation)

Table 2. The efficacy assessment of 12-item Oxford knee score in patients with Ayurved Siriraj Wattana Recipe group (Wattana) 900 mg/day and diclofenac group 75 mg/day from baseline to week 12; intention to treat analysis (n = 60)

12-item Oxford knee score	Wattana 900 mg/day (n = 30) mean (SD)	Diclofenac 75 mg/day (n = 30) mean (SD)	95% CI for difference	p-value
Pain scores				
Baseline	14.3 (2.9)	14.5 (3.9)	-1.6, 1.9	0.85
Week 2	12.3 (3.1)	12.6 (4.6)	-1.8, 2.3	0.79
Week 4	11.2 (3.4)	11.9 (4.5)	-1.4, 2.7	0.50
Week 8	9.8 (3.1)	10.4 (4.2)	-1.3, 2.5	0.56
Week 12	9.4 (3.1)	10.4 (4.2)	-0.9, 2.9	0.30
Function scores				
Baseline	18.0 (5.1)	18.3 (6.0)	-2.6, 3.1	0.85
Week 2	16.4(5.1)	16.8 (5.9)	-2.5, 3.2	0.80
Week 4	15.3 (4.5)	16.1 (6.1)	-2.0, 3.6	0.57
Week 8	14.4 (4.1)	14.5 (5.2)	-2.3, 2.5	0.91
Week 12	13.7 (3.6)	14.3 (5.7)	-1.9, 3.1	0.63

Analyses to test the superiority were based on the intention-to-treat (ITT) population
Statistical significance was evaluated using unpaired t-test
Values are expressed as mean (SD), 95% CI for difference and significant level at a p-value < 0.05

of 0.05 cm with no difference ($p > 0.05$). Table 3 represent Visual Analogue Scale (VAS) assessed pain for 900 mg/day Ayurved Siriraj Wattana Recipe was not significantly different from those for diclofenac 75 mg/day at 2, 4, 8, and 12 weeks ($p > 0.05$). In addition, Pain reduction associated with 900 mg/day Ayurved Siriraj Wattana Recipe was significantly similar as with 75 mg/day diclofenac at all assessments.

Secondary efficacy variables - patients' and physician's global assessment

At the end of the present study (12 weeks), globally efficacy assessment levels of patients with the Ayurved Siriraj Wattana Recipe group were moderately effective (19.6%) and very effective (19.6%) respectively, while patients with the diclofenac group were moderately effective assessment (17.6%). Also,

Table 3. Efficacy variable included 10-cm VAS that pain assessment at baseline and each follow-up visit obtained from Ayurved Siriraj Wattana Recipe group (Wattana) (900 mg/day) and diclofenac (75 mg/day)

VAS assessed pain	Wattana 900 mg/day mean (SD)	Diclofenac 75 mg/day mean (SD)	95% CI for difference	p-value
Baseline	6.63 (0.30)	6.58 (0.30)	-0.899, 0.807	0.91
Week 2	5.93 (0.22)	5.17 (0.35)	-1.594, 0.075	0.07
Week 4	5.48 (0.19)	5.58 (0.34)	-0.693, 0.896	0.79
Week 8	4.89 (0.26)	4.25 (0.39)	-1.568, 0.291	0.17
Week 12	4.37 (0.25)	4.42 (0.39)	-0.909, 0.973	0.94

Statistical significance was evaluated by using unpaired t-test
Values are express as mean (SD) and significant level at a p-value < 0.05

the patients' global efficacy assessment were not significantly different between both groups (p = 0.9), data not shown. Most of the subjects in both groups rated themselves as improved (59.6% to 61.8%).

At the end of the present study (12 weeks), globally efficacy assessment levels of patient with the Ayurved Siriraj Wattana Recipe group and the diclofenac group were moderately effective assessment by physician. Also, the physician's global efficacy assessment shown no significant differences between both groups (p = 0.95) data not shown. Most of the subjects in both groups rated by a physician as improved. (59.6%-61.8%)

Outcome measurement: safety variables

Hematological and biochemical laboratory evaluations

The blood tests between week 0 and week 12 revealed some changes in both groups, but the values were still within acceptable ranges and the changes had no clinical importance (Table 4, 5). There were no significant differences between baseline and week 12 values within the wattana group (p > 0.05). However, there were marginally higher in levels of aspartate amino transferase (AST) in the 900-mg tid. wattana group at the end of the present study (mean; 24.4 U/L) than week 0 (mean; 22.3 U/L) (p = 0.04).

There were no significant differences at baseline and week 12 values within the diclofenac group (p > 0.05). Although, there were mean increase in the percentage of eosinophils at the end of the present study (2.8), while at screening was 2.2 (p = 0.04). The number of white blood cells (WBC count) and the percentage of hematocrit were significantly decreased at week 12 compared with the baseline (week 0) measurements (Table 5). There were no significant changes of hematology and clinical chemistry observation in either group at baseline (p > 0.05) and the end of the present study.

Adverse drug reaction

In the present study, none of the serious adverse events (AEs) was considered to be related to the study drug (Table 6). Most adverse events were reported in the gastrointestinal system and consisted of gastrointestinal irritation, diarrhea. Other adverse events included generalized edema and rash. Diclofenac at 75 mg/day produced a significantly higher incidence of GI irritation and rash than did Ayurved Siriraj Wattana Recipe. The proportion of patients in the diclofenac group (6.6%) who withdrew from the present study was not significantly different than those for the Ayurved Siriraj Wattana Recipe (3.3%) group (p > 0.05).

Patients' and physician's global tolerability assessment

Globally safety assessment levels of most of the patients in both groups were good tolerant at week 12 that were evaluated by patients. In addition, the patients' global safety assessment were not significantly different between both groups (p = 0.15), data not shown.

Globally safety assessment levels of most of the patients in both groups were good tolerant at week 12 that were evaluated by physicians. In addition, the physician's global safety assessment were not significantly different between both groups (p = 0.30). Three-fourths of the subjects evaluated themselves to have well tolerance.

Discussion

Patients with knee OA usually have knee pain from the inflammatory process of the knee joints. As osteoarthritis is an incurable disease, hence the

Table 4. Laboratory-based evaluations of safety at baseline and week 12 within Ayurved Siriraj Wattana Recipe group (Wattana); intention to treat-LOCF analysis (n = 60)

Test	Wattana baseline	Wattana week 12	p-value
Hemoglobin (g/dL)	12.68 ± 1.14	12.63 ± 1.02	0.72
Hematocrit (%)	38.10 ± 3.40	38.11 ± 2.82	0.98
WBC count (x10^3/ul)	6.37 ± 1.09	6.39 ± 1.50	0.94
Platelet count (x10^3/ul)	258.90 ± 62.06	259.50 ± 63.00	0.95
Neutrophil (%)	55.40 ± 6.30	55.10 ± 6.10	0.37
Lymphocytes (%)	35.50 ± 5.70	35.70 ± 5.50	0.88
Monocytes (%)	6.19 ± 1.90	5.88 ± 1.93	0.46
Eosinophils (%)	2.70 ± 1.70	3.30 ± 2.96	0.27
Basophils (%)	0.55 ± 0.26	0.50 ± 0.30	0.36
FBS (mg/dl)	99.30 ± 14.90	102.70 ± 16.80	0.16
BUN (mg/dl)	12.60 ± 3.5	13.90 ± 4.50	0.09
Creatinine (mg/dl)	0.80 ± 0.20	0.78 ± 0.20	0.40
AST (SGOT) (U/L)	22.30 ± 4.90	24.40 ± 6.05	0.04*
ALT (SGPT) (U/L)	20.70 ± 9.10	20.30 ± 8.70	0.75

Data expressed as a mean ± SD and significant level at a p-value < 0.05

Table 5. Laboratory-based evaluations of safety at baseline and week 12 within diclofenac group; intention to treat-LOCF analysis (n = 60)

Test	Diclofenac baseline	Diclofenac week 12	p-value
Hemoglobin (g/dL)	13.00 ± 1.06	12.70 ± 1.07	0.08
Hematocrit (%)	39.50 ± 2.90	38.70 ± 2.95	0.02*
WBC count (x10^3/ul)	6.50 ± 1.60	5.90 ± 1.40	0.02*
Platelet count (x10^3/ul)	275.40 ± 47.00	279.00 ± 59.60	0.49
Neutrophil (%)	58.40 ± 8.90	57.20 ± 6.30	0.85
Lymphocytes (%)	33.20 ± 9.50	33.20 ± 6.50	0.99
Monocytes (%)	5.75 ± 1.86	6.29 ± 1.86	0.17
Eosinophils (%)	2.20 ± 1.70	2.80 ± 2.00	0.04*
Basophils (%)	0.45 ± 0.23	0.48 ± 0.20	0.46
FBS (mg/dl)	101.90 ± 15.90	101.20 ± 16.80	0.64
BUN (mg/dl)	14.30 ± 4.40	12.80 ± 4.20	0.05
Creatinine (mg/dl)	0.78 ± 0.18	0.77 ± 0.15	0.63
AST (SGOT) (U/L)	22.40 ± 5.80	23.10 ± 5.90	0.37
ALT (SGPT) (U/L)	23.10 ± 14.20	24.00 ± 14.70	0.29

Data expressed as a mean ± SD and significant level at a p-value < 0.05

Table 6. Incidence of adverse events (AEs) and treatment discontinuation caused by AEs during the 12-week treatment period

Events	Wattana (n = 30), n (%)	Diclofenac (n = 30), n (%)
Any AEs	2 (6.6)	3 (9.9)
Generalized edema	1 (3.3)	0
Gastro-intestinal irritation	0	2 (6.6)
Diarrhea	1 (3.3)	0
Rash	0	1 (3.3)
Discontinuation caused by AEs	1 (3.3)	2 (6.6)

Data are presented as number (%) of patients reporting events and significant level at p-value < 0.05

goal of treatment is to reduce pain and maintain mobility. The present study was done because there were evidences that *Derris scandens* Benth extracts, which are one of active compound in Ayurved Siriraj Wattana Recipe, had similar pharmacologic activities of anti-inflammatory properties and were safe[11-13]. The present study found that Ayurved Siriraj Wattana Recipe were efficacious and safe in patients with knee OA and similar to diclofenac. Diclofenac was chosen for being the comparator because it had an intermediate-acting period and could be used three times per day like Ayurved Siriraj Wattana Recipe. This could enhance the compliance of participants in taking the medication[14,15]. Furthermore, there were scientific evidences from meta-analysis that NSAIDs are statistically superior in reducing rest and walking pain compared with acetaminophen for symptomatic osteoarthritis. Additionally, no significant difference in safety was found between acetaminophen and NSAIDs[16].

There was a study demonstrating the efficacy of *Derris scandens* Benth extracts in alleviating pain in patients with symptoms of LBP[12]. Finally, the pain (visual analogue scale) scores of both groups at day 3 and day 7 significantly decreased compared to their baseline values. Additionally, there were no significant changes of blood chemistry in either group. In addition, there was study showing that *D. scandens* Benth extracts were efficacious and safe for the treatment of knee OA[2]. However, no study reported the efficacy of Ayurved Siriraj Wattana Recipe in patients with knee OA.

Using the 12-item Oxford knee score to compare the efficacy of knee OA between Ayurved Siriraj Wattana Recipe group and diclofenac group revealed no difference in pain and functional activity. The present study is notable for comparing the severity of knee OA in a population with the same ethnicity and culture. All other major variables such as age, BMI, sex, working style, underlying diseases are also similar between the two groups. Further work will be needed to determine the modifiable risk factors for knee OA.

Concerning safety, even though the number of patients with adverse events (AE) in both groups was not different ($p = 0.24$), the events of common AE of gastrointestinal (GI) irritation and rash were found to be more common in the diclofenac group This means that the Ayurved Siriraj Wattana Recipe is safe. GI irritation symptom was the most commonly found AE that caused patients to be unable to have NSAIDs[17]. No other serious AE was found, including changes in blood tests. The subjects were asked to have medicine thrice a day in order to have the same protocol. Moreover, most subjects evaluated themselves as improvement and satisfaction without notable difference between groups. The limitation of the present study was the open-labeled design due to limited budget and appearance drugs. Therefore, further research should be performed with the double-blinded design to confirm the effectiveness of Ayurved Siriraj Wattana Recipe without any bias. Ayurved Siriraj Wattana Recipe at a dosage of 900 mg/day also demonstrated overall improved globally tolerability assessment, with significantly fewer adverse events and withdrawals due to adverse events.

Conclusion

Overall, the present study suggests clinical benefits of thrice daily doses of 900 mg Ayurved Siriraj Wattana Recipe was improved upper gastrointestinal tract safety, compared with 75 mg/day diclofenac. No additional efficacy benefit was obtained from a 900-mg dose Ayurved Siriraj Wattana Recipe. Ayurved Siriraj Wattana Recipe at a dosage of 900 mg/day is as effective as diclofenac at a dosage of 75 mg/day in relieving mild to moderate osteoarthritis of the knee over 12 weeks that may offer a valuable option for some patients with joint pain and dysfunction.

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Potential conflicts of interest

None.

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การศึกษาทางคลินิกระยะที่ 2 ของยาวัฒนะ ตำรับอายุรเวทศิริราช เพื่อบรรเทาอาการข้อเข่าเสื่อมในผู้ป่วยโรคข้อเข่าเสื่อม

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ภูมิหลัง: *โรคข้อเข่าเสื่อมเป็นปัญหาทางสุขภาพที่พบบ่อยที่สุดในประเทศไทยและทั่วโลก ก่อให้เกิดการสูญเสียความสามารถในการทรงตัวด้วยสาเหตุจากความเจ็บปวดและการสูญเสียความสามารถในการใช้งาน การรักษาโรคข้อเข่าเสื่อมมีทั้งใช้ยาและไม่ใช้ยา โดยการรักษาด้วยยาต้านการอักเสบที่ไม่ใช่สเตียรอยด์ (NSAIDs) สามารถบรรเทาอาการปวดจากข้อเข่าเสื่อมได้แต่อาจก่อให้เกิดเหตุการณ์ไม่พึงประสงค์จากการใช้ยา ดังนั้นการเลือกใช้ยาจากสมุนไพรที่อาจมีประสิทธิผลและความปลอดภัยมากกว่าเป็นอีกทางเลือกหนึ่งในการรักษาโรคข้อเข่าเสื่อม ยาจากสมุนไพรได้มีการใช้อย่างแพร่หลายในหลายประเทศทั่วโลกซึ่งยาวัฒนะตำรับอายุรเวทศิริราชเป็นหนึ่งในยาหลายตำรับโบราณที่ใช้เรื่อยมาจนถึงปัจจุบันส่วนประกอบของยาวัฒนะตำรับนี้ มีความเกี่ยวข้องกับระบบต่าง ๆ ของร่างกาย เช่น ระบบภูมิคุ้มกัน ระบบทางเดินอาหาร และอาจมีฤทธิ์ต้านการอักเสบและฤทธิ์ต้านอนุมูลอิสระ*

วัตถุประสงค์: *วัตถุประสงค์หลักคือเพื่อเปรียบเทียบผลการรักษาจากแบบสอบถาม Oxford-12 ที่บ่งชี้ถึงความเจ็บปวดและการใช้งานของข้อเข่า 5 ระดับ วัตถุประสงค์รองคือ วัดความเจ็บปวดจากสเกล 0-10 การประเมินผลการรักษาโดยแพทย์และผู้ป่วยเอง เฝ้าระวังผลข้างเคียงจากการใช้ยาที่อาจเกิดขึ้น*

วัสดุและวิธีการ: *งานศึกษานี้จึงได้ดำเนินการเพื่อศึกษาประสิทธิผลและผลข้างเคียงที่อาจเกิดขึ้นได้ของยาวัฒนะตำรับอายุรเวทศิริราชเปรียบเทียบกับยาไดโคลฟีแนคเพื่อการบรรเทาอาการข้อเข่าเสื่อมโดยทำการทดลองแบบสุ่มเปิดเป็นเวลา 12 สัปดาห์ โครงการนี้ได้รับการรับรองจากคณะกรรมการจริยธรรมการวิจัยในคน คณะแพทยศาสตร์ศิริราชพยาบาล มหาวิทยาลัยมหิดล ก่อนเริ่มทำการศึกษา*

ผลการศึกษา: *ผู้ป่วยจำนวนทั้งสิ้น 60 ราย ถูกสุ่มแบ่งเป็นกลุ่มศึกษา 2 กลุ่ม โดยกลุ่มผู้ป่วย 30 คนสำหรับการรักษาด้วยยาวัฒนะตำรับอายุรเวทศิริราชขนาด 900 มิลลิกรัมต่อวันและกลุ่มผู้ป่วย 30 คน สำหรับรับการรักษาด้วยยาไดโคลฟีแนคขนาด 75 มิลลิกรัมต่อวัน จากการศึกษาพบว่า เวลา 12 สัปดาห์ที่ได้รับยา ผลการประเมินแบบสอบถาม Oxford-12 ในด้านความเจ็บปวด และการใช้งานระหว่างผู้ป่วยทั้งกลุ่มที่ได้รับยาวัฒนะตำรับอายุรเวทศิริราชและยาไดโคลฟีแนคไม่มีความแตกต่างกันในทางสถิติ ไม่พบความแตกต่างระหว่างความเจ็บปวด VAS ระหว่างผู้ป่วยทั้ง 2 กลุ่มศึกษา และไม่พบผลข้างเคียงจากการใช้ยาระหว่างผู้ป่วยทั้ง 2 กลุ่ม*

สรุป: *การศึกษานี้พบว่าทั้งแพทย์และผู้ป่วยให้คะแนนความพึงพอใจต่อผลการรักษาสูง จึงอาจสรุปได้ว่ายาวัฒนะตำรับอายุรเวทศิริราชเป็นอีกทางเลือกสำหรับรักษาผู้ป่วยอาการข้อเข่าเสื่อม*