Comparison of the Effectiveness between Generic and Original Form of Gabapentin for Pain Relief in Suspected Neuropathic Component of Low Back Pain

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Objective: *To compare effectiveness of the generic form of gabapentin with its original form.*
Material and Method: *A single-blind evaluation randomized controlled trial (RCT) of patients that were diagnosed with low back pain with suspected neuropathic component at the Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital were included in the present study. Patients were randomized into two treatment groups. The first group received gabapentin generic form (GGF) or Gabapentin Sandoz, whereas the other received gabapentin original form (GOF) or Neurontin. The primary endpoint was the Visual Analogue Scale (VAS) pain score. The secondary endpoints were the Thai version of the Oswestry low back pain disability index (ODI) score, lumbar spine's range of motion, safety profiles, and average medical cost. Non-inferiority was pre-specified at 20%. The amount of medication was increased to maintain VAS less than 40 mm and tapered off in case of adverse event.*
Results: *Forty-one patients, GGF 21 and GOF 20, had completed the study. At 8th week, the visual analogue scale (VAS) and ODI scores significantly decreased in both groups. Mean and standard deviation (SD) of VAS improvement were 31.4±22.1 mm for the GGF group versus 34.3±22.6 mm for the GOF group (p = 0.69), within pre-specified 20% non-inferiority margin (difference 2.9 mm 95% CI -17.7 mm, 11.8 mm). Mean ODI improvement was 11.1% for the GGF group versus 7.6% for the GOF group (p = 0.42), within pre-specified 20% non-inferiority margin, (difference 3.5, 95% CI = -12.3%, 5.3%). Both groups have significantly gained flexion of the lumbar spine. Both groups revealed similar safety profiles. The GGF group showed significantly lower average cost for medications (2,844 baht).*
Conclusion: *In comparison with the GOF (Neurontin) group, the non-inferior effectiveness for pain reduction and improvement of back function has been revealed in the GGF (Gabapentin Sandoz) group. Similar safety profiles were demonstrated in both groups. The average medication cost of GGF is much lower than GOF (4.67 times).*

Keywords: *Generic, Gabapentin, Non-inferiority trial, Low back pain, Neuropathic component*

J Med Assoc Thai 2014; 97 (7): 767-75
Full text. e-Journal: *http://www.jmatonline.com*

Neuropathic pain has been found in 20 to 35% of patients with chronic low back pain. Those with chronic low back pain usually have low quality of life due to associate co-morbidities that include depression, panic and anxiety disorders, and sleep disturbances[1]. The cost of treatment for patients with neuropathic low back pain is higher than those with non-neuropathic low back pain[2,3]. The most commonly recommended intervention for low back pain is pharmacotherapy[4-6]. The frequently prescribed medications are, namely, non-steroidal anti-inflammatory drugs (NSAIDs), skeletal muscle relaxants, and opioid analgesics[7-10]. These medications are used for treating chronic low back pain by focusing on nociceptive pain. Neuropathic pain component can be associated with chronic low back pain. It is possibly caused from the different pain-generating mechanisms. Hence, different therapeutic strategies have been proposed when neuropathic components are suspected as a part of pain generators. Antidepressants and anticonvulsants have been effectively used in patients having low back pain with neuropathic components[11].

Gabapentin, an anticonvulsant, the efficacy has been proven for pain improvement among patients with neuropathic pain. The anticonvulsant gabapentin has shown the efficacy of pain reduction among patients diagnosed with diabetic neuropathic pain and post herpetic neuralgia[12]. The efficacy of the drug has

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been studied in patients diagnosed with lumbar radiculopathy and lumbar spinal stenosis. The improvements in pain scores have been revealed[13-15]. In Thailand, gabapentin has been usually prescribed for patient having chronic back pain associated with lumbar radiculopathy; however, the high cost of gabapentin original form (GOF) has been found to be the problem for the patients. Gabapentin generic form (GGF) has recently been launched in Thailand with limited clinical evidences to prove GGF's effectiveness compare to GOF. The objective of the present study is to compare the effectiveness between GGF and GOF for pain relief in patients with suspected neuropathic component of low back pain. The effectiveness is determined by pain reduction and functional improvement. Moreover, the safety profiles and medication costs are compared between GGF and GOF group.

Material and Method

An experimental single-blind evaluation randomized controlled non-inferiority (NI) trial was conducted at the Department of Rehabilitation Medicine, King Chulalongkorn Memorial Hospital between August 2012 and February 2014. The study protocol had been approved by the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University.

Subjects

Adult patients aged between 18 and 75 years and diagnosed with low back pain were recruited. The causative lumbar pathologies were, namely, spondylosis, spondylolisthesis, radiculopathy, and herniated nucleus pulposus. The onset of low back pain was at least one month. The neuropathic component of low back pain was screened by the Thai version of DN4 (Douleur Neuropathique en 4 Questions)[16]. Patients must have at least two positive responses to the DN4 questions. Pain areas must be located in the lower back, buttock, and lower extremity. Patients must have moderate pain intensity assessed by visual analogue scale (VAS) that scored at least 40 mm. Discontinuation of previous anticonvulsants and antidepressants for at least two weeks was required. The exclusion criteria are having contraindications for gabapentin, hepatic or renal impairments, pregnancy, recently received spinal operation within six months, severe psychiatric disorder, or diagnosed with spinal infection, tumor located in the spinal area, or severe spinal trauma.

Treatment protocol

Eligible patients were allocated into two treatment groups by blocked randomization. GGF (Gabapentin Sandoz) was prescribed for the first group whereas GOF (Neurontin) was prescribed for the other group. The protocol comprised an 8-week period[15]. Gabapentin dosage was started with 100 mg on the first day, 200 mg on the second day, and 300 mg on the third day. Afterward the 300 mg daily gabapentin was continued for two weeks. Adjustment of gabapentin dosage is based on pain level (VAS) and adverse events every two weeks. The amount of medication was increased to maintain VAS less than 40 mm and tapered in case of presented adverse events. The effective dose of gabapentin was determined by two parameters, patients have VAS pain score less than 4, and patients have no need for using the other groups of medication for pain relief. Patients, who either have experienced serious adverse events or missed the follow-up more than two times, were considered as dropout. The details of rehabilitation program were remained for patients receiving rehabilitation program before starting the protocol. Furthermore, the rehabilitation naïve patients were requested for not joining the rehabilitation program during the study protocol. All participants were informed regarding the protocol's details and potential side effects occurring from gabapentin. Informed consents were signed by all participants before starting the trial.

Outcome measurement

The primary endpoint was the VAS pain score[13-15]. The secondary endpoints were: the Thai version of the Oswestry low back pain disability index (ODI) score, lumbar spine's range of motion, blood chemistry for hepatic and renal functions, adverse events, the frequency of using other groups of medications for pain relief and average treatment cost[15,17]. The change of VAS pain and ODI score were assessed for pre-specified 20% non-inferiority. Blinded assessment was performed by the first author. Hepatic function was assessed as serum glutamic oxaloacetic transaminase (SGOT) and serum glutamic pyruvic transaminase (SGPT), whereas renal function was assessed as serum creatinine (SCr) and blood urea nitrogen (BUN). Blood chemistries were immediately analyzed within 24 hours before starting medications and after completing the study protocol. The three other groups of medications for pain relief were acetaminophen based, NSAIDs, and opioid.

Statistical analysis

The data were analyzed by SPSS program version 17.0 for protocol analysis. The primary endpoint and secondary endpoints were compared between before and after 8-week intervention period in each group using paired t-test and compared between two groups using the unpaired t-test. The change of VAS pain and ODI score were analyzed by unpaired t-test to determine the range of 95% confidence interval. The demographic data, as categorical data and continuous data, were analyzed by unpaired t-test, or Pearson Chi-square test, Fisher's exact test respectively. Non-normal distributed data were analyzed using Mann-Whitney U test. Level of statistical significance was determined at *p*-value of less than 0.05.

Results

One hundred thirty seven patients were recruited into the present study. More than 90 patients were excluded due to the following factors, decline to join in the protocol, DN 4 score less than 2, VAS pain score less than 40 mm, severe co-morbidities, having spinal operation within six months, or aged more than 75 years. However, 41 patients were eligible to the protocol and randomized into GGF (n = 21) and GOF (n = 20). GGF group had one dropout patient due to discontinuing medication, whereas GOF group had two dropout patients due to rashes and discontinuing medication. After 8-week period of medication, the numbers of per protocol population were 20 and 18 patients in GGF and GOF groups respectively. The flowchart showing patients' progression through the study was demonstrated in Fig. 1.

Most eligible patients were female (n = 32, 78%). The average age was 54.4 years. Baseline data revealed that there was no significant difference between the two groups in every parameter as show in Table 1. The causes of low back pain were namely, herniated nucleus pulpous (n = 12, 29.27%), spondylolisthesis (n = 11, 26.83%), spinal stenosis (n = 10, 24.39%), spondylosis (n = 7, 17.07%), and other (n = 1, 2.47%). The number of patients having true neuropathic pain determined by DN 4 score greater than 4 were 14 and 13 patients in GGF and GOF groups respectively. As for the primary endpoint, there was a significant improvement of VAS pain score within group between pre- and post-treatment and between the two groups. The difference VAS score between both groups was 2.9 mm whereas 95% confidence interval (CI) was -17.7 and 11.8 mm. The effective gabapentin dosage was between 600 and 1,200 mg in both groups. The average effective dose were 700 mg in GGF group and 778.6 mg in GOF group (*p*-value = 0.46). Both groups revealed that 83% of patients used gabapentin at least 600 mg. The average duration until reaching the effective dose were 3.6 weeks in the GGF group and four weeks in the GOF group (*p*-value = 0.58). The ODI score, first secondary endpoint related to back function, had been significantly lower in both groups after the treatment. The difference of ODI score between both groups was 3.5% whereas 95% CI was -12.3% and 5.3%. The lumbar range of motion, second secondary endpoint related to back function, had been significantly improved only on flexion in both groups. The details of data had been demonstrated in Table 2 and Table 3.

Regarding other medications used for pain relief as rescue medications, acetaminophen and combination of acetaminophen and orphenadrine citrate (Norgesic) were the most commonly used in both groups. NSAIDs group was the second most

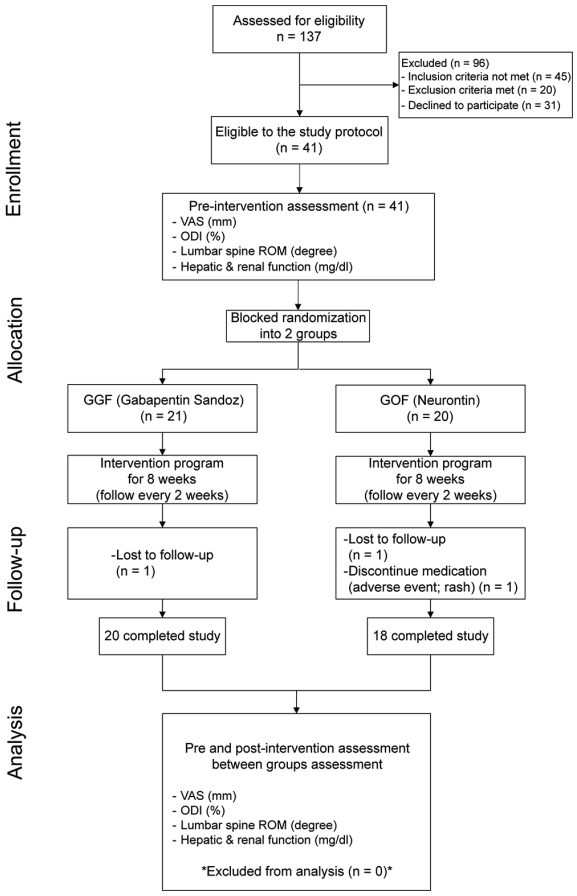

Fig. 1 Flowchart showing patient's progression through the study.

Table 1. The baseline data and comparison between treatment groups

Baseline data	Treatment groups		*p*-value
	GGF (Gabapentin Sandoz) n = 21	GOF (Neurontin) n = 20	
Age (years), mean ± SD	54.4±14.3	54.4±13.9	0.998[a]
Female, n (%)	15 (75.0%)	17 (94.4%)	0.184[c]
Underlying diseases, n (%)	12 (60.0%)	11 (61.1%)	0.944[d]
BMI (kg/m^2), mean ± SD	26.1±5.4	23.9±3.7	0.156[a]
Presented lumbar radiculopathy (from investigation), n (%)	12 (60.0%)	6 (33.3%)	0.100[d]
Duration of back pain (months), median (IQR)	6 (1-21)	8 (2-18)	0.534[b]
Previous treatment, n (%)	17 (85.0%)	16 (88.9%)	1.000[c]
VAS pain score (pre-intervention), mean ± SD	60.5±19.2	70.6±15.6	0.087[a]
Lumbar spine range of motion; ROM (degree), mean ± SD			
Flexion	75.1±19.4	82.2±14.5	0.251[b]
Extension	18.6±6.1	20.3±8.4	0.806[b]
Left bending	20.8±4.6	21.4±4.5	0.874[b]
Right bending	20.9±5.5	22.3±6.1	0.251[b]
Left rotation	51.0±12.4	51.1±13.5	0.979[a]
Right rotation	46.3±14.7	49.2±14.7	0.546[a]
ODI (%), mean ± SD	38.2±13.7	35.9±16.7	0.740[b]
SGOT (mg/dl), mean ± SD	24.5±5.9	22.7±8.8	0.331[b]
SGPT (mg/dl), mean ± SD	28.3±15.1	20.8±10.7	0.105[b]
BUN (mg/dl), mean ± SD	13.5±4.6	12.8±3.9	0.611[a]
Serum creatinine (mg/dl), mean ± SD	0.8±0.2	0.7±0.1	0.593[a]

GGF = gabapentin generic form; GOF = gabapentin original form; BMI = body mass index; VAS = visual analogue scale; ODI = Oswestry low back pain disability index score; SGOT = serum glutamic oxaloacetic transaminase; SGPT = serum glutamic pyruvic transaminase; BUN = blood urea nitrogen

[a] Unpaired t-test, [b] Mann-Whitney U test, [c] Fisher's exact test, [d] Pearson Chi-square test

Table 2. The change of VAS pain score and ODI score; pre- and post-treatment and between treatment groups

	Treatment groups		Mean of between group difference *p*-value[b] (95% CI)
	GGF (Gabapentin Sandoz) n = 21	GOF (Neurontin) n = 20	
VAS pain score			
Pre-treatment (mean ± SD)	60.5±19.2	70.6±15.6	
Post-treatment (mean ± SD)	29.2±16.3	36.3±21.6	
Change (mean ± SD)	-31.4±22.1	-34.3±22.6	2.9
p-value[a]	<0.001*	<0.001*	0.689
95% CI	-41.7 to 21.0	-45.5 to 23.0	-17.7 to 11.8
ODI			
Pre-treatment (mean ± SD)	38.2±13.7	35.9±16.7	
Post-treatment (mean ± SD)	27.1±10.9	28.3±14.0	
Change (mean ± SD)	-11.1±12.9	-7.6±13.8	-3.5
p-value[a]	0.001*	0.033*	0.422
95% CI	-17.2 to 5.0	-14.4 to 0.7	-12.3 to 5.3

[a] Paired t-test within treatment group, [b] Independent t-test of difference between groups

Table 3. Lumbar spine range of motion; comparison pre and post treatment and between treatment groups

Lumbar spine range of motion	Treatment groups		Mean of between group difference *p*-value[b] (95% CI)
	GGF (Gabapentin Sandoz) n = 21, mean ± SD	GOF (Neurontin) n = 20, mean ± SD	
Flexion			
Pre-treatment	75.1±19.4	82.2±14.5	
Post-treatment	86.3±16.8	88.7±13.6	
Change	11.3±11.8	6.4±10.4	4.8
p-value[a]	<0.001*	0.018*	0.193
95% CI	5.7 to 16.8	1.3 to 11.6	-2.5 to 12.2
Extension			
Pre-treatment	18.6±6.1	20.3±8.4	
Post-treatment	20.4±6.6	19.7±7.3	
Change	1.8±6.8	-0.6±8.4	2.4
p-value[a]	0.244	0.782	0.341
95% CI	-1.4 to 5.0	-4.7 to 3.6	-2.6 to 7.4
Left bending			
Pre-treatment	20.8±4.6	21.4±4.5	
Post-treatment	22.3±6.1	22.5±5.0	
Change	1.5±4.3	1.1±5.3	0.4
p-value[a]	0.132	0.396	0.790
95% CI	-0.5 to 3.5	-1.5 to 3.7	-2.7 to 3.6
Right bending			
Pre-treatment	20.9±5.5	22.3±6.1	
Post-treatment	23.2±3.9	22.1±4.5	
Change	2.2±5.6	-0.2±4.2	2.4
p-value[a]	0.092	0.824	0.140
95% CI	-0.4 to 4.9	-2.3 to 1.9	-0.8 to 5.7
Left rotation			
Pre-treatment	51.0±12.4	51.1±13.5	
Post-treatment	50.5±12.4	53.9±11.6	
Change	-0.5±10.9	2.8±11.3	-3.2
p-value[a]	0.855	0.311	0.376
95% CI	-5.5 to 4.6	-2.8 to 3.4	-10.5 to 4.1
Right rotation			
Pre-treatment	46.3±14.7	49.2±14.7	
Post-treatment	48.1±10.8	51.3±14.5	
Change	1.8±11.5	2.1±14.5	-0.3
p-value[a]	0.486	0.546	0.946
95% CI	-3.6 to 7.2	-5.1 to 9.3	-8.9 to 8.3

[a] Paired t-test within treatment group, [b] Independent t-test of difference between groups

commonly used, whereas opioid was rarely used in both groups. The frequencies of rescue medication usage in GGF and GOF groups were 184 and 127 times. After completing the protocol, the less frequent usage of rescue medication was significantly revealed in both groups. Ten and seven participants completed the protocol without using any rescue medications in GGF and GOF groups. The total cost of gabapentin using in GGF group and GOF were 15,537 baht and 65,184 baht. The average cost of gabapentin using in GGF group was significantly lower than GOF group about 4.67 times (777±224 baht vs. 3,621±821 baht).

As for the safety profiles, there was no significant difference of hepatic and renal function between pre and post treatment and between the two groups as Table 4. Somnolence was the most common adverse event reported in GGF group (65%) and GOF group (66.6%). The other adverse events were constipation (GGF 25%, GOF 13.3%), dizziness (GGF 10%, GOF 6.7%), nausea, and vomiting (GOF

Table 4. Hepatic and renal function; comparison pre- and post- treatment and between groups

Blood chemistry	Treatment groups		Mean of between group difference *p*-value[b] (95% CI)
	GGF (Gabapentin Sandoz) n = 21	GOF (Neurontin) n = 20	
SGOT			
Pre-treatment	24.5±5.9	22.7±8.8	
Post-treatment	25.1±9.7	21.6±8.7	
Change	0.7±6.5	-1.1±5.1	1.8
p-value[a]	0.660	0.369	0.363
95% CI	-2.4 to 3.7	-3.7 to 1.4	-2.1 to 5.6
SGPT			
Pre-treatment	28.3±15.1	20.8±10.7	
Post-treatment	28.0±15.5	18.7±10.0	
Change	-0.4±12.5	-2.1±8.1	1.8
p-value[a]	0.901	0.282	0.613
95% CI	-6.2 to 5.5	-6.1 to 1.9	-5.2 to 8.8
BUN			
Pre-treatment	13.5±4.6	12.8±3.9	
Post-treatment	12.9±3.8	13.1±3.7	
Change	-0.7±4.1	0.3±3.8	-0.9
p-value[a]	0.486	0.760	0.475
95% CI	-2.6 to 1.3	-1.6 to 2.2	-3.5 to 1.7
Creatinine			
Pre-treatment	0.76±0.18	0.74±0.13	
Post-treatment	0.76±0.15	0.73±0.14	
Change	-0.005±0.088	0.008±0.079	-0.004
p-value[a]	0.822	0.659	0.889
95% CI	-0.046 to 0.037	-0.048 to 0.031	-0.051 to 0.059

[a] Paired t-test within treatment group, [b] Independent t-test of difference between groups

6.7%) and rash (GOF 6.7%). One patient in GOF group needed to discontinue medication due to rash.

Discussion

Effectiveness of gabapentin on pain relief among patients having chronic radiculopathy was mentioned in a few studies. However, there were limited evidences that these patients had true neuropathic pain[13-15]. The present study attempted to recruit either patients having true neuropathic pain or patients having suspected neuropathic pain using the Thai version of DN 4 using the cutoff DN4 at two scores[16]. Two out of three patients in each group had true neuropathic pain determined by DN4 score that was more than 4. The authors would like to explore the effectiveness of gabapentin in either true neuropathic pain or suspected neuropathic pain because the Thai version of DN 4 was rarely used in the routine clinical practice as prerequisite for prescribing gabapentin. Patients complaining of radicular pain and did not respond well either with acetaminophen based medications or NSAIDs will be prescribed with gabapentin as the therapeutic diagnosis of neuropathic component instead of using either questionnaire or diagnostic tool for determining whether patients have true neuropathic pain. Hence, the present study's protocol has been designed similarly to the routine clinical practice.

The main purpose of the present study was to compare the effectiveness between the generic and original form of gabapentin by focusing on the three main outcomes, namely, pain reduction, functional improvement and the safety profiles. Firstly, as for the pain reduction, the author followed the VAS pain score, the effective dose, and the rescue medications. GGF group have had pain reduction within 20% pre-specified margin; thus, gabapentin generic form provided non-inferior effectiveness of pain relief in comparison with the original form. Furthermore, the effective dose and duration reaching the effective dose remained similar in both generic and original forms. Interestingly, some patients in both groups still uses acetaminophen based and NSAIDs. These

findings indicated that back pain for these patients was originated partly from nociceptive mechanism. In comparison with the GOF group, the frequency of rescue medication usage seemed higher in the GGF group; however, the percentage of participants using rescue medication seemed to be lower in GGF group (GGF = 50% vs. GOF = 61.11%).

As for the secondly functional improvement, both treatment groups have significantly gained in functional improvement, determined by improved lumbar spine's flexion, and reduced ODI score. Improvement of back flexion could be possibly explained by the most common cause of back pain, i.e., herniated nucleus pulposus. As for VAS pain score, the reduction of ODI score was within 20% pre-specified margin for GGF group. Finally, as for the safety profiles, both treatment groups had similar safety profiles by having indifferent percentage of adverse events and unchanging in hepatic and renal functions. Severe adverse events had not been reported in both treatment groups. The participants could be tolerated with the adverse events and continued taking the medication along 8-week study protocol. The more intensity of adverse events has been initially reported, then intensity was lessen and well tolerated by participants.

The medication cost was another main concerned issue in the present study. GGF group had much lower cost than GOF group as 4.67 times. The costs of these recue medications have not been obtained in the present study because these factors were unable to be controlled. According to the usage of rescue medication, the GGF group has higher frequency whereas the GOF group has higher number of participants. The authors finally recommend that prescribing the generic form will be required before original form regarding economic status of Thailand especially in the condition that gabapentin is reimbursed by the government. However, the switchback to original form should be allowed in the cases that there was no good response with the generic form demonstrated by unchanged VAS pain scores and using high amount the other kinds of pain-relief medication. This limitation of the present study was small sample size due to the specific inclusion criteria that leaded to exclude many recruited participants. The inclusion criterion mainly affected the number of participants was discontinuing the anticonvulsants and antidepressants for at least two weeks prior. Many recruited participants declined to join this protocol due to that reason.

Conclusion

In comparison with the GOF group, the non-inferior effectiveness for pain reduction and back function improvement has been revealed in the GGF group. The similar safety profiles are demonstrated in both groups. The medication cost of GGF is much lower than GOF (4.67 times).

What is already known on this topic?

Gabapentin, the anticonvulsant, has proven efficacy on pain improvement among patients having low back pain with neuropathic component. In Thailand, gabapentin has been usually prescribed for patient having chronic back pain associated with lumbar radiculopathy; however, the high cost has been found among patients having treated by gabapentin original form or Neurontin.

What this study adds?

Gabapentin generic form or Gabapentin sandoz provided the non-inferior effectiveness for pain reduction and back function improvement when it is compared to Neurontin. The similar safety profiles are demonstrated in both groups. The average medication cost of Gabapentin sandoz is much lower than Neurontin (4.67 times). This information will ensure clinicians for prescribing generic gabapentin to their patients. This information will be benefit for our current healthcare economic situation.

Acknowledgement

The authors wish to thank Associate Professor Jariya Boonhong and Mr. Wasan Punyasang for giving us helpful suggestions on statistical analysis.

Potential conflict of interest

The present study was funded by Novartis (Thailand) Limited; however, the research process was not be influenced by any conflict of interest.

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การศึกษาถึงประสิทธิภาพของยากาบาเพนตินชนิดต้นแบบเปรียบเทียบกับชนิดสามัญในการบรรเทาปวดในภาวะปวดหลังที่สงสัยว่าเกี่ยวข้องกับระบบประสาท

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วัตถุประสงค์: *เปรียบเทียบประสิทธิภาพของยากาบาเพนตินชนิดสามัญกับชนิดต้นแบบ*

วัสดุและวิธีการ: *เป็นการศึกษาแบบ single blinded evaluation randomized controlled trial (RCT) ของผู้ป่วยที่มีภาวะปวดหลังที่สงสัยว่าเกี่ยวข้องกับระบบประสาท ที่ฝ่ายเวชศาสตร์ฟื้นฟู โรงพยาบาลจุฬาลงกรณ์ ผู้ป่วยถูกแบ่งเป็น 2 กลุ่ม แบบสุ่ม กลุ่มแรกได้รับกลุ่มยากาบาเพนตินชนิดสามัญ หรือ กาบาเพนติน แซนดอส ขณะที่อีกกลุ่มได้รับยากาบาเพนตินชนิดต้นแบบ หรือ นิวรอนติน การศึกษามีตัวชี้วัดหลักคือ คะแนนความปวด visual analogue scale (VAS) ตัวชี้วัดรองดังนี้ คะแนนแบบสอบถาม Oswestry low back pain disability index (ODI) ฉบับภาษาไทย พิสัยการเคลื่อนไหวของหลัง ข้อมูลทางด้านความปลอดภัย และค่าใช้จ่ายเฉลี่ยของยา กำหนดระดับความด้อยกว่าไว้ก่อนที่ 20% ปรับยาทุก 2 สัปดาห์ โดยเพิ่มขนาดยาเพื่อให้มี VAS ต่ำกว่า 40 มม. และลดขนาดยาหากมีอาการไม่พึงประสงค์*

ผลการศึกษา: *ผู้ป่วยทั้งหมด 41 ราย แบ่งเป็นกลุ่มยาสามัญ 21 ราย และกลุ่มยาต้นแบบ 20 ราย ณ สัปดาห์ที่ 8 ทั้งสองกลุ่มมีคะแนนความปวด VAS และ ODI ลดลงอย่างมีนัยสำคัญ ค่าเฉลี่ยและค่าเบี่ยงเบนมาตรฐานของ VAS ที่ลดลงสำหรับกลุ่มยาสามัญเท่ากับ 31.4±22.1 มม. และกลุ่มยาต้นแบบเท่ากับ 34.3±22.6 มม. (p = 0.69, ค่าที่แตกต่างระหว่างกลุ่มคือ 2.9 มม. ค่าช่วงความเชื่อมั่น 95% = -17.7 มม., 11.8 มม.) ซึ่งไม่เกินระดับความด้อยกว่าที่กำหนด ค่า ODI ที่ลดลงสำหรับกลุ่มยาสามัญเท่ากับ 11.1% และกลุ่มยาต้นแบบ 7.6% (p = 0.51, ค่าที่แตกต่างระหว่างกลุ่มคือ 3.5 ค่าช่วงความเชื่อมั่น 95% = -12.3%, 5.3% ซึ่งไม่เกินระดับความด้อยกว่าที่กำหนด ทั้งสองกลุ่มมีพิสัยการเคลื่อนไหวของหลังในด้านก้มตัวเพิ่มขึ้นอย่างมีนัยสำคัญและมีข้อมูลด้านความปลอดภัยเหมือนกัน กลุ่มยาสามัญมีราคายาเฉลี่ยต่ำกว่าอย่างมีนัยสำคัญ (2,844 บาท)*

สรุป: *เมื่อเปรียบเทียบกับยากาบาเพนตินต้นแบบ (นิวรอนติน) ยากาบาเพนตินชนิดสามัญ (กาบาเพนติน แซนดอส) มีประสิทธิภาพการลดปวดและเพิ่มความสามารถในด้านของการใช้งานในชีวิตประจำวันไม่ด้อยกว่ายาต้นแบบ ทั้งสองกลุ่มมีข้อมูลทางด้านความปลอดภัยไม่ต่างกัน กลุ่มยาสามัญมีค่าใช้จ่ายเฉลี่ยของยาต่ำกว่ากลุ่มยาต้นแบบ (4.67 เท่า)*