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Efficacy and tolerability of eperisone versus tizanidine in patients suffering from low back pain with muscle spasm

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ABSTRACT

Background: Low back pain (LBP), a high prevalent condition, is usually associated with 'muscle spasm' that is responsible for giving rise to pain. Eperisone hydrochloride is widely used for treatment associated muscle stiffness and pain. The aim of the study was to compare the efficacy and safety of eperisone tablets 50 mg three times daily versus tizanidine 2 mg tablets thrice daily for the treatment of low back pain with muscle spasm.

Methods: The study was carried in 50 patients from a private hospital at Mumbai. Only patients satisfying the inclusion criteria were enrolled into the study. Subjects suffering from low back pain with spasm were divided in two groups. The patients were then followed up on Day-14.

Results: Patients receiving eperisone showed a mean value of 16.48 ± 1.15 in the Roland Morris low back pain and disability questionnaire both groups on day 1 and was reduced to 7.92 ± 1.15 (51.94%) on day 7 and 2.56 ± 1.53 (84.46%) on day 14. Similarly, the patients in tizanidine group had mean value of 15.96 ± 1.62 on day 1, which was reduced to 6.76 ± 1.66 (57.64%) on day 7, and 2.88 ± 1.92 (81.95%) on day 14, as similar to eperisone group. There was no statistical significant difference between the two groups, (p>0.05) for pain at rest, pain at night, restriction of movement, changes in stiffness, changes in numbness and changes in tenderness. There was statistical significant difference between the two groups, (p<0.05) for pain on movement and kinesalgia.

Conclusions: Eperisone was found to be comparable to Tizanidine in improving the signs and symptoms of changes in pain Self-assessment by the patient on different applied parameters.

Keywords: Eperisone, Low back pain, Tizanidine spasm

INTRODUCTION

Low back pain (LBP), a high prevalent condition among middle aged population, is usually associated with 'muscle spasm' that is responsible for giving rise to pain as well as its persistence. Muscle spasm is an involuntary, painful contraction of muscles that interferes with the function and cause of muscular disorder. Therefore, centrally acting skeletal muscle relaxants, also called lissive drugs, are commonly used for its treatment.

Sometimes these are combined with NSAIDs. The use of centrally acting skeletal muscle relaxants, though efficacious, is associated with frequent development of dose-related adverse drug reactions like sedation, impairment of voluntary motor functions and ataxia. So there is an urgent need for newer better drugs for treatment of conditions associated with muscle spasm.¹

International surveys of low back pain reported that 1-month prevalence was 19-43% and point prevalence was

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15-30%. The estimated worldwide lifetime prevalence of low back pain varies from 50% to 84%.

The occurrence of low back pain in India is also alarming with nearly 60% of the people in India have suffered from low back pain at some time during their lifespan. Low back pain also restricts mobility, interferes with normal functioning and results in lifelong pain and permanent disability. In India, most of the low-income group people are engaged in physically demanding jobs which may increase the risk of low back pain and disability. Low back pain also affects the quality of life (QOL) of not only the women themselves, but their families as well.²

Treatment of LBP is challenging and guidelines recommend medications with proven benefits. Also patients' preference should be considered in the treatment of pain. The first-line medications for the symptomatic treatment of LBP are acetaminophen/paracetamol or nonsteroidal anti-inflammatory drugs (NSAIDs) including traditional or selective cyclooxygenase-2 (COX-2) inhibitors, followed by opioid analgesics or tramadol, and muscle relaxants. Muscle relaxants have been mainly used for treating musculoskeletal conditions or spasticity. Further, the potential for abuse eperisone, an analgesic and centrally acting muscle relaxant has been in use for the treatment of LBP. Clinical studies have demonstrated efficacy of eperisone in the treatment of LBP. The AEs of eperisone include GI disturbances (nausea, epigastric pain and vomitus), vertigo, and light-headedness.

Eperisone, however, is found to be associated with low incidence of subjective side effects. In consideration to the challenges associated with choosing the most appropriate treatment for LBP and the limitations associated with paracetamol, NSAIDs, opioids, and muscle relaxants, we had done a study to assess the efficacy and safety of eperisone in the treatment of LBP. Study also sought to draw a conclusion whether eperisone finds its place in the treatment of LBP and thus aiding the clinicians in choosing the appropriate drug for LBP.³

In clinical practice, muscle relaxants of short and intermediate duration of action should be preferred, since such agents carry the least risk of residual neuromuscular block. New muscle relaxants are available today. The centrally acting muscle relaxants reduce the increased muscle tonus and inhibit the hyperactive reflexes by antagonizing the receptor activation coupled to the excitation of motor functions or by acting on the receptors related to inhibitory functions. Eperisone hydrochloride is widely used for treatment of diseases with associated muscle stiffness and pain.³

The objective of this study was to compare the efficacy and safety of Eperisone hydrochloride tablets 50 mg three times daily versus Tizanidine 2 mg tablets thrice daily for the treatment of patients suffering from low back pain with muscle spasm.

METHODS

The study was carried in 50 patients from a private hospital at Mumbai. Only patients satisfying the inclusion criteria were enrolled into the study. Potential study subjects were divided during the first visit to either of the two groups. The patients were then followed up on Day-

Clinical diagnosis

Patients suffering from low back pain with spasm.

Inclusion criteria

Patients in the age group of 18-65 years, Patients ready to give informed consent and Patients who were clinically stable.

Exclusion criteria

Pregnant or lactating females, female patient with childbearing age not using medically approved contraceptives, Patient with known suspected history of hypersensitivity to any of the trial drugs, Patients with impaired liver function, defined as SGOT>2.0 times the upper limit of normal, Patients with impaired kidney function, confirmed by serum creatinine >2.0 mg/dl, Patients with presence of active peptic ulcer or any other disease affecting the absorption of drug, Patients suffering from hematologic or endocrine disorders. Patients on concurrent therapy like (Antacids, H2 receptor antagonists, Proton pump inhibitors. Medications which affect motility like tricyclic antidepressants or laxatives. Medications that cause reflux disease symptoms like alendronate or nifedipine. Patients already taking or have taken in the past the investigational medication. Back pain due to following conditions (acute disc herniation, osteoarthritis or spinal stenosis, spondylolisthesis, ankylosing spondylitis, infection, malignancy). On clinical examination following has to be ruled out like Instability problem, Nerve root signs, Radiculopathy and Postural problem.

Study design

Patients were randomly divided into two groups. Each patient as per randomization received Eperisone hydrochloride tablets or tizanidine tablets daily for a period of 14 days.

Dosage

Patients randomized into two groups received eperisone 50 mg or tizanidine 2 mg per day.

Study schedule and plan

The patients were enrolled after informed and written consent as per the inclusion and exclusion criteria.

Current medical history and diagnosis were noted during the first visit. Patient was assigned to receive eperisone 50 mg or tizanidine 2 mg. After enrollment into study, follow-up was done on day-7. At initial visit, following the general examination, blood sample was withdrawn to estimate Hb, RBC, CBC, E.S.R, SGOT, total bilirubin, serum creatinine and blood sugar (fasting). Similar procedure was repeated at the end of the treatment i.e. Day-7 and day-14. Following clinical examination and signs and symptoms were noted, these were past history of treatment with anti-inflammatory/analgesic agents. A thorough neurologic examination was performed to assess deep tendon reflexes, sensation and muscle strength. Peripheral pulses were also being assessed and the abdomen was palpated to search for organomegaly. The physician was assess joint and muscle flexibility in the lower extremities, examine the entire spine and assess stance, posture, gait and straight leg rising.

Administration of 'Roland disability questionnaire' at the start and end of therapy: This was a 24 point questionnaire and patient was instructed to mark the point when your back hurts with pain and mention the severity, type, duration, and many more parameters on all the 3 visits and at last the mean value is calculated from all the three visit and statistics applied to observe the significant difference within the group from baseline to day 7 and day 14, and also compared between the two groups.

Patients were advised to maintain a 'pain diary' which contains the different questions related to pain like when did the pain begin? When did the pain end, radiating or non-radiating?

The symptoms of back pain were scored based on the 'visual analogue score' as 0-10 for severity (0-no pain, 1-mild discomfort, 2-moderate discomfort, 3-mild pain, 4-mild - moderate pain, 5- moderate pain, 6- moderate-severe pain, 7- severe pain, 8- very severe pain, 9- very very severe pain, and 10-agony).

Clinical efficacy

The symptoms of back pain were recorded as following parameters Pain at rest, Pain at night, Restriction of movement, Pain on movement, Stiffness, Numbness, Tenderness and Kinesalgia. Visual analogue score from 0-10 for severity (0-no pain, 1- mild discomfort, 2-moderate discomfort, 3- mild pain, 4- mild-moderate pain, 5- moderate pain, 6- moderate-severe pain, 7-severe pain, 8- very severe pain, 9- very very severe pain, and 10- agony). Rating points were given to the patients' pain symptoms according to the severity on each visit and the mean value is calculated from each visit and compared to observe the statistical significant difference within the group and also between the two groups.

Adverse effects if any were recorded in detail. Compliance was evaluated by asking the patient to bring balance medicine during follow up visits. A minimum of

80% compliance was taken as satisfactory and only those patients with compliance more than 80% were considered for efficacy analysis. The medication was prescribed to the patient and s/he was advised to report any adverse event, if any and return for follow up on the assigned days. The patients were also being advised to report any symptomatic worsening of the disease.

Assessment of safety

All reported adverse drug reactions in the study population were analyzed for their severity, duration and relation to the study drug.

Statistics

The results were statistically analyzed by students t test, paired t test, Wilcoxon signed rank test, Mann Whitney test, and Chi-square test.

RESULTS

Demographic characteristics

Table 1 shows that mean age of the cases were 55.24 years and 55.88 years in, eperisone group and tizanidine group which were same, and difference was not significant. Average weight of the patients was comparable. There was no dropout in eperisone group and tizanidine group. A total of 50 patients (25 in eperisone and 25 in tizanidine group) completed the study and were included for statistical analysis.

Table 1: Demographic profile.

Parameters	Eperisone	Tizanidine
No. of patients	25	25
Age (years)(a)		
Mean	55.24	55.88
SD	±4.05	±3.04
Range	18-65 years	18-65 years
Weight (kg)(a)		
Mean	69.44	69.48
SD	±3.92	±2.31
Range	42-76 kg	38-78 kg
Sex (%) ^(b)		
Male	13	09
Female	12	16

p>0.05 there was no statistical Significant difference between the two groups.

Efficacy parameters

The efficacy parameters were changes in pain Self-assessment by the patient and the symptoms of back pain were recorded as following parameters pain at rest, pain at night, restriction of movement, pain on movement, stiffness, numbness, tenderness, kinesalgia. Visual analogue score from 0 (Absent) to 10 (Severe).

Table 2: Comparison of changes in pain selfassessment by Roland Morris low back pain and disability questionnaire in both groups.

Duration in days	Eperisone	Tizanidine
Basal	16.48±1.15	15.96±1.62
Day 7	7.92±1.15 (51.94%)*	6.76±1.66 (57.64%)*
Day 14	2.56±1.53 (84.46%)	2.88±1.92 (81.95%)

p>0.05- there was no statistical Significant difference between the two groups. *p<0.05- there was statistical significant difference within the two groups.

The number of episodes of back pain and pain intensity were scored based on the visual analogue score as 0-10 for severity (0-no pain, 1- mild discomfort, 2- moderate discomfort, 3- mild pain, 4- mild-moderate pain, 5- moderate pain, 6- moderate-severe pain, 7- severe pain,

8- very severe pain, 9- very very severe pain, and 10-agony) was measured as presence or absence.

As seen from Table 2 shows that the patients receiving eperisone showed a mean value of 16.48 ± 1.15 in the Roland Morris low back pain and disability questionnaire both groups on day 1 and was reduced to 7.92 ± 1.15 (51.94%) on day 7 and 2.56 ± 1.53 (84.46%) on day 14. Similarly, the patients in tizanidine group had mean value of 15.96 ± 1.62 on day 1, which was reduced to 6.76 ± 1.66 (57.64%) on day 7, and 2.88 ± 1.92 (81.95%) on day 14, as similar to eperisone group. There was no. statistical significant difference between the two groups but there was statistical significant difference within the two groups (p<0.05)*. Table 3 describes the changes in different pain and stiffness parameters between the two groups.

Table 3: Comparison of different pain and stiffness parameters.

Duration in days	Eperisone	Tizanidine	P value				
Changes in pain at rest							
Basal	2.6±0.57	3.4±1					
Day 7	1.24±0.43 (52.30%*)	1.88±1.23(44.70%)*	p>0.05 between the two groups. *p<0.05 within the two groups				
Day 14	0.12±0.33 (95.38%)	0.68±1.06 (80.0%)	p<0.03 within the two groups				
Changes in pain at n	ight						
Basal	3.12±0.72	3.04±0.73					
Day 7	0.8±0.91 (74.35%)*	0.56±0.76 (81.57%)*	p>0.05 between the two groups. *p<0.05 within the two groups				
Day 14	0.04±0.2 (98.71%)	0.12±0.33 (96.05%)	p<0.03 within the two groups				
Changes in restriction of movement							
Basal	3.8±0.5	4.32±0.9	0.051.4				
Day 7	1.8±0.64 (52.63%)*	2.36±1.03 (45.37%)*	p>0.05 between the two groups. *p<0.05 within the two groups				
Day 14	0.56±0.58 (85.26%)	0.84±0.94 (80.55%)	*p<0.03 within the two groups				
Changes in pain of movement							
Basal	3.96±0.35	4.72±1.17					
Day 7	1.72±0.45 (56.56%)*	2.44±1.26 (48.30%)*	p<0.05 between the two groups. *p<0.05 within the two groups				
Day 14	0.48±0.50 (87.87%)	0.84±1.17 (82.20%)	*p<0.03 within the two groups				
Changes in stiffness							
Basal	4.32±0.80	3.92±0.4	0.051				
Day 7	2.16±0.98 (50.0%)	1.84±0.55 (53.06%)	p > 0.05 between the two groups. *p<0.05 within the two groups				
Day 14	0.84±1.02 (80.55%)*	0.72±0.54 (81.63%)*	*p<0.03 within the two groups				
Changes in numbnes	SS						
Basal	2.28±0.61	2.6±0.70	0.051				
Day 7	1±0.57 (56.14%)	1.6±0.70 (38.46%)*	p>0.05 between the two groups. *p<0.05 within the two groups				
Day 14	0.2±0.40 (91.22%)*	0.72±0.73 (72.30%)	*p<0.03 within the two groups				
Changes in tenderne	ess						
Basal	5.28±0.54	5.72±0.73	0.051				
Day 7	2.6±0.64 (50.75%)*	3.04±0.97 (46.85%)	p>0.05 between the two groups. *p<0.05 within the two groups				
Day 14	1±0.5 (81.06%)	1.52±1.04 (73.42%)	p<0.03 within the two groups				
Changes in kinesalgi	a						
Basal	2.36±0.7	4±1					
Day 7	1.08±0.4 (54.23%)	2.28±1.24 (43.0%)	p<0.05 between the two groups. *p<0.05 within the two groups				
Day 14	0.16±0.37 (93.22%)*	1.04±1.20 (74.0%)*	p<0.03 within the two groups				

Changes in pain at rest

pain at rest was reduced from mean value of 2.6 ± 0.57 on day 1 to 1.24 ± 0.43 (52.30%) after 07 days of administration of eperisone, and 0.12 ± 0.33 (95.38%) after day 14. Similarly, tizanidine reduced the pain at rest score from mean value of 3.4 ± 1 on day 1 to 1.88 ± 1.23 (44.70%) on day 7, and further 0.68 ± 1.06 (80.0%) on day 14 (p>0.05). There was no statistical significant difference between the two groups, (p>0.05), but there was statistical significant difference within the two groups (p<0.05)*.

Changes in pain at night

In patients receiving eperisone, with a mean of 3.12 ± 0.72 showed pain at night on Day 1. Further, 0.8 ± 0.91 (74.35%) showed improvement in pain at night on Day 7, and 0.04 ± 0.2 (98.71%) improvement on Day 14, In patients receiving tizanidine, 3.04 ± 0.73 showed pain at night on Day 1, followed by 0.56 ± 0.76 (81.57%) improvement on Day 7, and 0.12 ± 0.33 (96.05%) improvement on Day 14. There was no statistical significant difference between the two groups, (p>0.05), but there was statistical significant difference within the two groups (p<0.05)*.

Changes in restriction of movement

In patients receiving eperisone, with a mean of 3.8 ± 0.5 showed restriction of movement on Day 1. Further, with a mean 1.8 ± 0.64 (52.63%) showed improvement in restriction of movement on Day 7, and 0.56 ± 0.58 (85.26%) on Day 14, In patients receiving tizanidine, with a mean of 4.32 ± 0.9 showed restriction of movement on Day 1, followed by 2.36 ± 1.03 (45.37%) improvement on Day 7, and 0.84 ± 0.94 (80.55%) on Day 14. There was no statistical significant difference between the two groups, (p>0.05), but there was statistical significant difference within the two groups (p<0.05)*.

Changes in pain of movement

In patients receiving eperisone, with a mean of 3.96 ± 0.351 show pain of movement on Day 1. Further, 1.72 ± 0.45 (56.56%) showed improvement in pain of movement on Day 7, and 0.48 ± 0.50 (87.87%) on Day 14. In patients receiving tizanidine, 4.72 ± 1.17 show pain of movement on Day 1, followed by 2.44 ± 1.26 (48.30%) improvement on Day 7, and 0.84 ± 1.17 (82.20%) improvement on Day 14. There was statistical significant difference between the two groups, (p<0.05), and also there was statistical significant difference within the two groups (p<0.05)*.

Changes in stiffness

In patients receiving eperisone, with a mean value of 3.92 ± 0.4 showed stiffness on Day 1. Further, 1.84 ± 0.55 (53.06%) showed improvement in stiffness on Day 7, and

 1.84 ± 0.55 (81.63%) improved on Day 14. In patients receiving tizanidine, 4.32 ± 0.80 showed stiffness on Day 1, followed by 2.16 ± 0.98 (50.0%) showed improvement on Day 7, and 0.84 ± 1.028 (80.55%) improved on Day 14. There was no statistical significant difference between the two groups, (p>0.05), but there was statistical significant difference within the two groups (p<0.05)*.

Changes in numbness

In patients receiving eperisone, with a mean of 2.28 ± 0.61 showed numbness on Day 1. Further, 1 ± 0.57 (56.14%) showed improvement in numbness on Day 7, and 0.2 ± 0.40 (91.22%) improved on Day 14. In patients receiving tizanidine, 2.6 ± 0.70 showed numbness on Day 1, followed by 1.6 ± 0.70 (38.46%) showed improvement on Day 7, and 0.72 ± 0.73 (72.30%) improved on Day 14. There was no statistical significant difference between the two groups, (p>0.05), but there was statistical significant difference within the two groups (p<0.05)*.

Changes in tenderness

In patients receiving eperisone, with a mean of 5.28 ± 0.54 showed tenderness on Day 1. Further, 2.6 ± 0.64 (50.75%) showed improvement in tenderness on Day 7, and 1 ± 0.5 (81.06%) improved on Day 14. In patients receiving tizanidine, 5.72 ± 0.73 showed tenderness on Day 1, followed by 3.04 ± 0.97 (46.85%) showed improvement on Day 7, and 1.52 ± 1.04 (73.42%) improved on Day 14. There was no statistical significant difference between the two groups, (p>0.05), but there was statistical significant difference within the two groups (p<0.05)*.

Changes in kinesalgia

In patients receiving eperisone, with a mean of 2.36 ± 0.7 showed Kinesalgia on Day 1. Further, 1.08 ± 0.4 (54.23%) showed improvement in Kinesalgia on Day 7, and 0.16 ± 0.37 (93.22%) improved on Day 14. In patients receiving tizanidine, 4 ± 1 showed Kinesalgia on Day 1, followed by 2.28 ± 1.24 (43.0%) showed improvement on Day 7, and 1.04 ± 1.20 (74.0%) improved on Day 14. There was statistical significant difference between the two groups, (p<0.05), and also was statistical significant difference within the two groups (p<0.05)*.

Efficacy assessment

According to investigator assessment for efficacy (Table 4) 15 (62.5%) of total cases had an "excellent" improvement followed by 09 (37.5%) "good" in eperisone. In tizanidine group, only 07 (29.16%) of total cases had an "excellent" improvement followed by 16 (66.66%) "good" and 01 (4.16%) "poor".

Table 4 as per the patient's own assessment, 17 (70.83%) of total cases was rated "excellent", 07 (29.16%) "good" and 00 (0%) "poor" in eperisone. In the tizanidine group

07 (29.16%) of total cases was rated "excellent" and 14

(58.33%) as "good" and 03 (12.5%) as "poor".

Table 4: Efficacy and tolerability by physicians and patients.

	Eperisone		Tizanidine		D 1			
	No.	%	No.	%	P-value			
Overall assessment of efficacy of treatment by physicians								
Excellent	15	62.5%	07	29.16%				
Good	09	37.5%	16	66.66%	p>0.05, between the two			
Poor	00	00%	01	4.16%	groups			
Total	24	100%	24	100%				
Overall assessment of efficacy of treatment by patients								
Excellent	17	70.83%	07	29.16%	_			
Good	07	29.16%	14	58.33%	p<0.05, between the two			
Poor	00	00%	03	12.5%	groups			
Total	24	100%	24	100%				
Overall assessmen	t of tolerabil	ity of treatment by inves	stigators					
Excellent	17	70.83%	05	20.83%				
Good	05	20.83%	14	58.33%	p<0.05, between the two			
Poor	02	8.33%	05	20.83%	groups			
Total	24	100%	24	100%				
Overall assessmen	Overall assessment of tolerability of treatment by patients							
Excellent	17	70.83%	06	25.0%				
Good	05	20.83%	11	45.83%	p<0.05, between the two			
Poor	02	8.33%	07	29.16%	groups			
Total	24	100%	24	100%				

Tolerability assessment

According to investigators assessment for tolerability (Table 4) 17 (70.83%) of the total cases had "excellent" safety and 05 (20.83%) showed "good" safety and 02 (8.33%) as "poor" in group eperisone. In the tizanidine group 05 (20.83%) of total cases was rated "excellent" and 14 (58.33%) as "good" and 05 (20.83%) as "poor".

According to patient's assessment for tolerability (Table 4), 17 (70.83%) of the total cases had "excellent" safety and 05 (20.83%) showed "good" safety and 02 (8.33%) as "poor" in group eperisone. In the tizanidine group 06 (25.0%) of total cases was rated "excellent" and 11 (45.83%) as "good" and 07 (29.16%) as "poor".

DISCUSSION

The results of five studies (3 RCTs and 2 case series) suggest that eperisone intervention (7-14 days) may be effective in patients with acute LBP compared to placebo/thicolchiocoside/diazepam and also in before and after treatment studies.³⁻⁷

Eperisone intervention improved both pain and physiological measures in acute LBP patients. Treatment with eperisone for 4 weeks in chronic LBP patients also

improved the pain; non-significant to McKenzie therapy and similar to tizanidine. 8,9 Regarding safety and tolerability, the incidence of AEs was significantly less in acute LBP patients treated with eperisone when compared to those treated with thiocolchicoside and diazepam. In a placebo-controlled trial4, less number of acute LBP patients (n=22) experienced AEs in eperisone group as compared to placebo (n=29). This may be due to the fact that average consumption of rescue (paracetamol 500 mg) medication was significantly higher in the placebo group. Chronic LBP patients on eperisone (16.6%) showed numerically less dropouts due to AEs compared to tizanidine (30%), and a better adherence to the therapy. 4

Since, the evidence from the present review on the efficacy of eperisone for acute/chronic LBP is of low to moderate quality due to the small number of included studies and short duration, it is therefore difficult for us to suggest a definitive conclusion for the role of eperiosne in the treatment of LBP. Our results indicate that eperisone is an effective muscle relaxant drug with potency similar to that of other molecules, such as Tizanidine, which are currently used in the management of low back pain due to a contraction of spinal muscles. Eperisone is a new muscle relaxant compound with a pattern of activities slightly different from that of Tizanidine.

Present study had several limitations. The present study reveals that eperisone may be effective in improving pain and physiological outcomes in acute LBP patients. However, due to a small number of patients, more well-designed RCTs of good quality with a larger sample size and longer follow-up period are needed to confirm the clinical benefits of eperisone in the treatment of acute or chronic LBP with or without spasm.

CONCLUSION

Eperisone was found to be comparable to Tizanidine in improving the signs and symptoms of changes in pain Self-assessment by the patient on different applied parameters. The compliance of eperisone was found to be satisfactory. The global assessment for efficacy and safety for eperisone was also found to be similar to tizanidine.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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