

## Original Research Article

# Z-track technique reduces pain at the injection site, drug leakage, post-injection gluteal inflammation in Pritchard regimen for severe pre-eclamptic patients: findings from a randomized controlled trial

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**Received:** 05 August 2022

**Revised:** 02 September 2022

**Accepted:** 13 September 2022

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## ABSTRACT

**Background:** This study was conducted to compare the effect of Z track versus standard technique of intramuscular (IM) administration of magnesium sulfate (MgSO<sub>4</sub>) on level of pain at the injection site, drug leakage, post-injection gluteal inflammation in Pritchard regimen.

**Methods:** 60 antenatal patients with pre-eclampsia (PE) admitted in the labour room were randomized for IM administration of MgSO<sub>4</sub> by Z track technique (received all injections by Z track method) and standard technique group (received all injections by standard method). The primary outcomes were level of pain assessed by numerical rating scale, drug leakage measured by sterilized blotting paper technique and gluteal inflammation assessed by transparent grid sheet.

**Results:** The level of pain at the injection site and drug leakage after each injection significantly increased from the 1<sup>st</sup> injection (p<0.05) to the 8<sup>th</sup> injection in both groups. Z track group experienced significantly less pain (3<sup>rd</sup> and 5<sup>th</sup> injection, p<0.05), drug leakage (p<0.05) and inflammation (both buttocks, p<0.05) compared to the standard group.

**Conclusions:** A significant decrease in drug leakage and gluteal inflammation was observed in the Z track group. Though there was no statistically significant difference in the level of pain in both groups, the pain experienced by the Z track group was comparatively less.

**Keywords:** Drug leakage, Level of pain at the injection site, Pritchard regimen, Post-injection gluteal inflammation, Z track technique

## INTRODUCTION

Hypertensive disorders are responsible for severe morbidity, long term disability and even mortality (7-8%).<sup>1</sup> PE and eclampsia are the major cause for the suboptimal maternal and perinatal outcome. Globally PE complicates 2-8% of pregnancies and affects 2-4% of first-time pregnancies in the developed countries.<sup>2,3</sup> It is advocated that MgSO<sub>4</sub> should be used for the prevention and management of convulsions in patients of pre-

eclampsia with severe features or eclampsia.<sup>4,5</sup> There are different regimens of MgSO<sub>4</sub> administration and two regimens are widely recommended and used, The Pritchard and the Zuspan regimen.<sup>6-9</sup> In the Pritchard regimen, the patient receives repeated IM injections of MgSO<sub>4</sub> which results in pain, inflammation and infection at the injection site.<sup>6,7</sup>

The present study aimed to assess the effect of the Z track technique of administration of Pritchard regimen on the

primary outcomes such as level of pain at the injection site, drug leakage, post-injection gluteal inflammation and on the secondary outcome-occurrence of seizure in pre-eclamptic patients.

## METHODS

A prospective randomized controlled study was conducted on 60 antenatal women with PE. The antenatal women were recruited between October 2020 to December 2020 from the labour ward, Obstetrics and Gynaecology department of Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, India. The study was approved by the Institute Ethical Committee and registered at the Clinical Trials Registry- CRTI/2020/05/025165.

The sample size was calculated using [www.openepi.com](http://www.openepi.com), according to the study by Yilaz et al.<sup>22</sup> The mean difference of drug leakage in the experimental group was  $6.93 \pm 4.62$  and in the control group, it was  $10.03 \pm 3.69$ . The number of study participants needed for the study with a confidence level of 95%, test power of 80%, and the effect size of 0.741 (Cohen's d) was estimated at 29 in each group. In this study 30 antenatal women with PE were enrolled in each group.

Randomization plan was created on 13 October 2020 at 3:14:35 p.m. through [www.randomization.com](http://www.randomization.com) by research guide and allocation concealment was done by a person who had no direct relation to the study. Eighty subjects were randomized into two blocks using seed 5158. Allocation concealment was guaranteed by the use of sequentially numbered, opaque and sealed envelopes.

### Inclusion and exclusion criteria

Antenatal women with PE > 20 weeks of gestation admitted in the labour ward willing to participate in the study were included. PE with altered sensorium and who already received the loading dose of MgSO<sub>4</sub> from other hospitals were excluded.

Antenatal women with PE with severe features admitted in the labour ward requiring MgSO<sub>4</sub> have described the objectives of the study and screened for eligibility criteria by the researcher herself. A patient information sheet that included all the details of the study was given to the study participants and recruited after taking informed written consent. Study participants were randomized into Z track (experimental) and standard (control) group by employing the computer-generated random numbers with allocation concealment. Socio-demographic profile, Clinical profile including obstetrical data and biophysical data were collected and recorded on the day of recruitment.

A total of eight injections of MgSO<sub>4</sub> were administered in both groups, including the loading dose (10 gm of 50% of MgSO<sub>4</sub>, divided into 5 gm each buttock) maintenance

dose of 5 gm of 50% MgSO<sub>4</sub> (10 ml + 1 ml of 2% lignocaine) in alternate buttocks every 4<sup>th</sup> hour till 24 hours after termination of pregnancy or the last seizure whichever was later. In which the Z track group received all 8 injections by Z track technique to ventrogluteal site and standard group received all 8 injections by standard technique to dorsogluteal site by using 22 G x 38 mm needle. Before administering each dose of injection toxicity of the MgSO<sub>4</sub> was excluded by the presence of knee jerk, urine output of 25 ml per hour and respiratory rate of 12 per minute.

### Procedure

Patients in the Z track group were made to lie on their side with the knee flexed. Ventrogluteal injection site identified by placing the palm over the greater trochanter so that index finger points the anterior superior iliac spine, thumb towards genital area and spread the middle finger to make V shape.<sup>10</sup> In the Z track technique, the skin and the subcutaneous tissue were dragged by approximately 1 inch by an ulnar border of the hand, held firmly while the needle was inserted 90° into the muscle.<sup>11</sup> Aspiration is done to exclude the accidental introduction of needle into the blood vessel and the drug was injected at a speed of 10 seconds per ml. The pulled tissues and skin were released to the normal position once the medication was injected and the needle was withdrawn.

Patients in the standard method were made to lie on their side with the knee flexed. Dorsogluteal site ensured by identifying the posterior iliac spine and greater trochanter of the femur and line was drawn connecting both structures. An imaginary vertical line from the middle point of the first line was drawn to mark injection site.<sup>12</sup> The needle was inserted 90° into the muscle, aspiration is done to exclude the accidental introduction of needle into the blood vessel and the drug was injected at a speed of 10 s per ml without pulling the skin or tissue denoted as standard technique in this study.

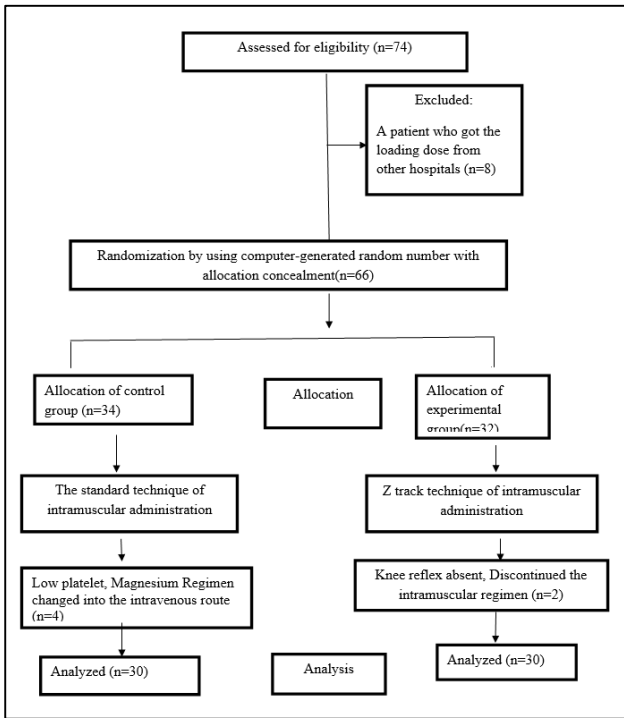
IM injections were administered by the graduate nurses who got comprehensive training and demonstration of the protocol. Before the administration of the injection by the graduate nurses, the return demonstration based on a structured checklist was ensured by the researcher. Immediately after each injection, the level of pain was assessed by using a numerical pain rating scale, which shows the intensity of current, best and worst pain levels on a scale ranging from 0 (absence of pain) to 10 (intolerable pain) having excellent reliability and the needle insertion site was gently pressed by the sterilized blotting paper.<sup>13,14</sup> The area of soakage on the blotting paper was measured in cm<sup>2</sup>. Post injection gluteal inflammation was assessed after 24 hours of the last injection by marking the swelling, assessed by placing a transparent grid sheet over the marked area and measured in cm<sup>2</sup>. The study participants were observed for seizure during the period of the prophylactic treatment and after

2 days of completing the regimen. A checklist was used to assess this variable.

Statistical analysis of the collected data in this study was carried out by using the statistics program IBM SPSS 20.0. For descriptive statistics mean and standard deviation, percentage were used to explain the data. The normalcy of the continuous data was checked by the Shapiro-Wilk test. For comparing both groups chi-square, Fisher’s Exact test and unpaired t-test were applied. For comparing mean scores of both groups Mann Whitney U test, independent t-test was computed. For repeated measure analysis of variance, the Fried man test and for the pair-wise analysis Fried man post hoc Dunn test were used. P value <0.05 considered statistically significant.

**RESULTS**

A total of 60 patients with preeclampsia were enrolled in the study (consort diagram shown in Figure 1).



**Figure 1: Consort diagram of the study.**

Table 1 summarizes the demographic and clinical characteristics of the study participants in both groups, the characteristics were comparable. The mean age of the study participants was 28.5 (6.5) and 26.97 (4.8) in the Z track and standard group respectively. The mean BMI of both groups were not statistically different (p=0.33). More than half of the study participants from both groups had a gestational period of 37-40 weeks (p=1.00). The majority of the study participants in the Z track group (70%) and standard group (63.3%) were primigravidas. 7 study participants (77.8%) from the Z track group had a history of abortion and previous history of PE and

eclampsia whereas in the standard group it was 54.5%, 63.3% respectively. More than half of the study participants in the Z track group (60.0%) and standard group (63.3%) terminated their index pregnancy by LSCS.

**Table 1: Socio-demographic and clinical characteristics.<sup>1</sup>**

Variables	Group		P value
	Z track technique (n=30)	Standard technique (n=30)	
Age (years)	28.50±6.51	26.97±4.86	0.306 <sup>a</sup>
BMI, kg/m <sup>2</sup>	24±3.66	24.9±3.55	0.339 <sup>a</sup>
<b>Period of gestation (in weeks)</b>			
21-24	--	1 (3.3)	1.00 <sup>b</sup>
25-28	2 (6.7)	2 (6.7)	
29-32	4 (13.3)	4 (13.3)	
33-36	8 (26.7)	8 (26.7)	
37-40	16 (53.3)	15 (50.0)	
<b>Gravida</b>			
Primi	21 (70.0)	19 (63.3)	0.58 <sup>c</sup>
Multi	9 (30.0)	11 (36.7)	
<b>Abortion (n=20)</b>			
Yes	7 (77.8)	6 (54.5)	0.374 <sup>b</sup>
No	2 (22.2)	5 (45.5)	
<b>Previous history of pre-eclampsia and eclampsia (n=20)</b>			
Yes	7 (77.8)	4 (36.4)	0.092 <sup>b</sup>
No	2 (22.2)	7 (63.3)	
<b>Method of childbirth of current pregnancy</b>			
NVD	12 (40.0)	11 (36.7)	0.791 <sup>c</sup>
LSCS	18 (60.0)	19 (63.3)	

<sup>1</sup>Data were expressed in frequency(percentage) or mean±SD; <sup>a</sup>Independent t-test, <sup>b</sup>Fisher’s Exact test, <sup>c</sup>Chi-square test; Abbreviations: BMI, body mass index.

**Table 2: Level of pain at the injection site during each injection of Pritchard regimen in each group.**

No. of injections	Level of pain at the injection site median (IQR)		P value
	Z track technique n=30	Standard technique n=30	
1 <sup>st</sup>	6 (2)	6 (1)	0.339 <sup>a</sup>
2 <sup>nd</sup>	6 (1)	6.50 (2)	0.165 <sup>a</sup>
3 <sup>rd</sup>	6 (1)	7 (2)	0.032 <sup>a</sup>
4 <sup>th</sup>	6.50 (1)	7 (1)	0.066 <sup>a</sup>
5 <sup>th</sup>	7 (1)	7 (1)	0.038 <sup>a</sup>
6 <sup>th</sup>	7 (2)	7 (1)	0.171 <sup>a</sup>
7 <sup>th</sup>	8 (1)	8 (1)	0.737 <sup>a</sup>
8 <sup>th</sup>	8 (2)	8 (2)	0.944 <sup>a</sup>
<b>P value</b>	<0.001 <sup>b</sup>	<0.001 <sup>b</sup>	

<sup>a</sup>Mann Whitney U test; <sup>b</sup>Friedman test.

Table 2 expresses the comparison of the level of pain among the study participants in both groups after each injection. The level of pain was significantly less in the Z track group when compared to the standard group during the third (p=0.03) and fifth (p=0.03) injection. On longitudinal analysis, it was found that the level of pain was significantly increasing from the first injection to the eighth injection in both groups (p<0.001). Though there was an increase in the pain in every subsequent injection, The post hoc analysis showed that pain was significantly

increased from the 5<sup>th</sup> injection (p=0.012) in the standard group and the 7<sup>th</sup> injection (p<0.001) in the Z track group (Table 3). The level of pain among the study participants in the Z track (experimental) and standard (control) group during the course of the Pritchard regimen depicted in Figure 2. There was a total of 240 injections in the Z track and standard group respectively. The mean level of pain observed in the Z track group (6.77±1.07) was less than standard group (7.008±1.067) at the p value of 0.002.

**Table 3: Fried man post hoc Dunn test of the level of pain during the course of Pritchard regimen in each group.**

Level of pain			
Z track technique (n=30)		Standard technique (n=30)	
Sample pair	P value	Sample pair	P value
1 <sup>st</sup> injection versus 7 <sup>th</sup> injection	<0.001	1 <sup>st</sup> injection versus 5 <sup>th</sup> injection	0.012
1 <sup>st</sup> injection versus 8 <sup>th</sup> injection	<0.001	1 <sup>st</sup> injection versus 6 <sup>th</sup> injection	<0.001
		1 <sup>st</sup> injection versus 7 <sup>th</sup> injection	<0.001
		1 <sup>st</sup> injection versus 8 <sup>th</sup> injection	<0.001

**Table 4: Drug leakage during each injection of Pritchard regimen in each group.**

No. of injections	Drug leakage in cm <sup>2</sup> Median (IQR)		P value
	Z track technique (n=30)	Standard technique (n=30)	
1 <sup>st</sup>	6 (5.25)	15 (10)	0.001 <sup>a</sup>
2 <sup>nd</sup>	9 (4.25)	17 (9.25)	0.001 <sup>a</sup>
3 <sup>rd</sup>	11 (4.25)	17 (7.5)	0.001 <sup>a</sup>
4 <sup>th</sup>	12 (6)	19 (8)	0.001 <sup>a</sup>
5 <sup>th</sup>	13 (6.5)	22.50 (13.25)	0.001 <sup>a</sup>
6 <sup>th</sup>	11 (7)	20.50 (14.25)	0.001 <sup>a</sup>
7 <sup>th</sup>	15 (10.75)	24 (13.5)	0.001 <sup>a</sup>
8 <sup>th</sup>	19 (12.25)	25.50 (17.5)	0.003 <sup>a</sup>
<b>P value</b>	<0.001 <sup>b</sup>	<0.001 <sup>b</sup>	

<sup>a</sup>Mann Whitney U test; <sup>b</sup>Friedman test

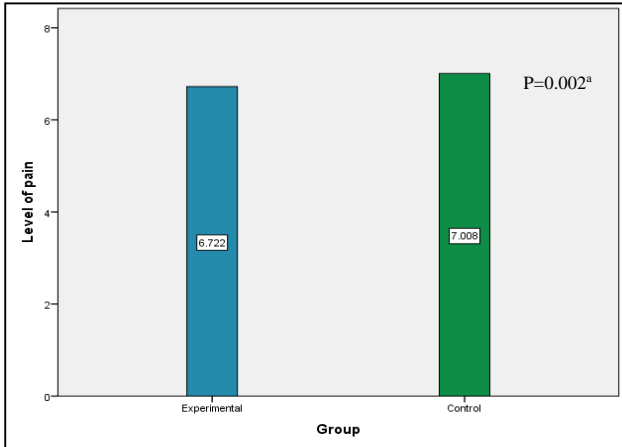
**Table 5: Fried man post hoc Dunn test of drug leakage during Pritchard regimen in each group.**

Drug leakage			
Z track technique (n=30)		Standard technique (n=30)	
Sample pair	P value	Sample pair	P value
1 <sup>st</sup> injection versus 3 <sup>rd</sup> injection	0.03	1 <sup>st</sup> injection versus 4 <sup>th</sup> injection	0.009
1 <sup>st</sup> injection versus 4 <sup>th</sup> injection	<0.001	1 <sup>st</sup> injection versus 5 <sup>th</sup> injection	<0.001
1 <sup>st</sup> injection versus 5 <sup>th</sup> injection	0.01	1 <sup>st</sup> injection versus 6 <sup>th</sup> injection	<0.001
1 <sup>st</sup> injection versus 6 <sup>th</sup> injection	<0.001	1 <sup>st</sup> injection versus 7 <sup>th</sup> injection	<0.001
1 <sup>st</sup> injection versus 7 <sup>th</sup> injection	<0.001	1 <sup>st</sup> injection versus 8 <sup>th</sup> injection	<0.001
1 <sup>st</sup> injection versus 8 <sup>th</sup> injection	<0.001		

**Table 6: Post injection gluteal inflammation after the course of Pritchard regimen in each group.**

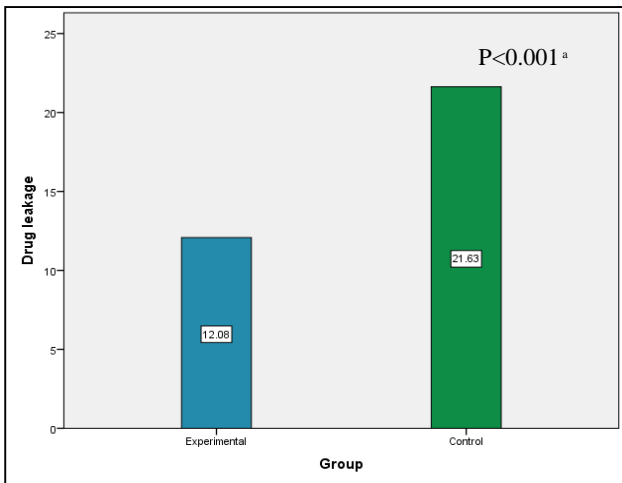
Side of the buttock	Post injection gluteal inflammation in cm <sup>2</sup> Mean± SD		P value
	Z track technique (n=30)	Standard technique (n=30)	
Right side of the buttock	80.17±20.45	100.60±21.23	<0.001 <sup>a</sup>
Left side of the buttock	82.63±21.01	102.07±21.23	0.001 <sup>a</sup>

<sup>a</sup>Independent t-test



**Figure 2: Level of pain among the study participants in Z track (experimental) and standard (control) group during the course of Pritchard regimen.**

<sup>a</sup>Independent t-test.



**Figure 3: Drug leakage among the study participants in Z track (experimental) and standard (control) group during the course of Pritchard regimen in cm<sup>2</sup>.**

<sup>a</sup>Independent t-test.

The comparison of drug leakage (in cm<sup>2</sup>) among the study participants in the Z track and the standard group expressed in Table 4. The minimum drug leakage was recorded after the first injection and maximum drug leakage observed at the eighth injection in both groups. The maximum drug leakage recorded in the Z track group was 19 (12.25) and in the standard group, it was 25.50 (17.5). The drug leakage was significantly less in the Z track group as compared to the standard group from the first to eighth injection. On longitudinal analysis, it was found that the drug leakage was significantly increased from the first to the eighth injection in both groups (p<0.001). Table 5 shows the pair-wise analysis of drug leakage observed from the first to eighth injection. In Z track group drug leakage was increasing significantly from the third injection when compared with the first injection whereas in the standard group the significance increase started at the 4<sup>th</sup> injection. The drug leakage

among the study participants in the Z track and standard group during the course of the Pritchard regimen illustrated in Figure 3. There was a total of 240 injections in the experimental and control group respectively. The mean drug leakage observed in the experimental group (12.08±6.24 cm<sup>2</sup>) was less than the control group (21.63±9.66 cm<sup>2</sup>) at the p value of 0.001.

Post injection gluteal inflammation (both left and right side) among study participants in both groups summarized in Table 6. The inflammation was recorded in cm<sup>2</sup>. The inflammation in both sides was significantly lesser in the Z track group when compared to the standard group. Post injection gluteal inflammation at the right side was recorded as 80.17±20.45 and 100.60±21.23 in the Z track and standard group respectively (p=0.001). None of the study participants experienced a seizure during the study period.

**DISCUSSION**

Feto-maternal morbidity and mortality due to PE and eclampsia can be reduced by early identification and prompt care. The Zuspan regimen and Pritchard regimen of MgSO<sub>4</sub> have been used for seizure prophylaxis in PE and eclampsia.<sup>5</sup> Pritchard regimen is known for injection associated complications like pain, drug leakage, infection and inflammation at the injection site.<sup>6,7</sup> The maintenance doses of the MgSO<sub>4</sub> are considered very painful because of the damage to the tissues as a complication that causing the pain.<sup>15</sup>

The study result revealed that the level of pain after the 3<sup>rd</sup> and 5<sup>th</sup> injections was significantly less (p<0.05) in the Z track group. Though there was no statistically significant difference was in the level of pain in other injections in both groups, the pain experienced by the Z track group was less. Possible explanations for the high level of pain reported by the study participants are, a massive volume (11 ml) of MgSO<sub>4</sub>, administration of injection at the frequency of every 4<sup>th</sup> hourly, subjective feeling. The probable explanation for less pain in the Z track technique in ventrogluteal muscle are the lateral pulling of the skin and subcutaneous tissue initiates and stimulates peripheral receptors causing a reduction in transmission and perception of pain, a lesser amount of subcutaneous tissue than dorsogluteal site reduces the probability of prescribed drug being administered to the subcutaneous tissue, increased absorption, proper distribution of the medication into the vascular muscle fibres in ventrogluteal site favour the success of IM injection.<sup>16</sup> Other non-pharmacological interventions such as acupressure, lavender oil inhalation can be coupled with the technique of the i.m. injection of MgSO<sub>4</sub> for reducing the pain level.<sup>17,18</sup> The study conducted by Kim, Keen and Kara et al reported that there was no significant difference in the severity of felt pain experienced by the patients after i.m. injections by the Z track and standard technique, though there was a retardation in the felt pain after i.m. injection by the Z track technique.<sup>19-21</sup>

In this study, a statistically significant decrease was found in drug leakage and post-injection gluteal inflammation after the i.m. administration of MgSO<sub>4</sub> by the technique of Z track at the significance of  $p < 0.05$ . Similar studies conducted by Yilmaz et al, Mac Gabhann, Najafidolatabad et al reported that the Z track technique was more effective in reducing drug leakage, bruising, rate of ecchymosis.<sup>22-24</sup> Z track preventing the return flow of the injected MgSO<sub>4</sub> into the subcutaneous tissue by making the route of the needle into a zig-zag shape thus helps to seal the injected MgSO<sub>4</sub> within the muscle, facilitating more absorption and lowering the development of complications such as drug leakage and post-injection gluteal inflammation.<sup>22</sup>

There was no occurrence of seizure observed among study participants in the Z track and standard group during and after 24 hours of completing the prophylactic treatment with MgSO<sub>4</sub> hence no statistical test was computed. The standard technique of i.m. injection is known for drug leakage and post-injection gluteal inflammation at the injection site can hamper the full dose of prescribed medication being injected and retard the anticipated benefit of the therapeutic regimen hence the occurrence of the seizure was monitored. And it is recommended that for assessing this particular variable a study can be conducted including large study participants.

This study was conducted on MgSO<sub>4</sub> injection therefore it is not generalized to other drugs and is therefore considered the limitation of the study.

The analysed data of this study showed that a significant decrease in drug leakage and gluteal inflammation in the Z track group. Though there was no statistically significant difference in the level of pain in both groups, the pain experienced by the Z track group was comparatively less.

## CONCLUSION

The study concluded that the Z track technique of i.m. injection of MgSO<sub>4</sub> was effective in minimizing the drug leakage, reducing the post-injection gluteal inflammation compared with the standard technique. Hence the i.m. injection of the MgSO<sub>4</sub> may be administered by the Z track technique to reduce the i.m. injection-related complication of the Pritchard regimen in patients with severe PE. Since the technique of Z track is a simple method, nurses can be easily practiced at the bedside. As the intervention was not statistically significant in reducing the level of pain at the injection site, non-pharmacological interventions can be coupled with Z track administration.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee and was registered at the Clinical Trials Registry-CRTI/2020/05/025165*

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**Cite this article as:** Babu JJ, Venkadalakshmi V, Chopra S, Dhandapani M. Z-track technique reduces pain at the injection site, drug leakage, post-injection gluteal inflammation in Pritchard regimen for severe pre-eclamptic patients: findings from a randomized controlled trial. *Int J Res Med Sci* 2022;10:2190-6.