



## Clinical Evaluation of Dexamethasone Pills on Side Effects of Mandibular Third Molars Surgery

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### ABSTRACT

Most mandibular third molars will be in need of surgical removal due to common signs of pain and infection after a period of time. There are different methods for controlling post-surgical pain and swelling including the use of anti-inflammatory drugs such as corticosteroids during and after surgery. One main drug is called dexamethasone which is kind of corticosteroid. There are different dosages in dental treatment for reducing post-surgical complication. Dexamethasone has considerable effect on reducing pain, edema and trismus. This study aimed to show clinical effect of dexamethasone on side-effects of mandibular third molars surgery. This study was performed as a double blind randomized clinical trial method on 75 patients who were admitted in the surgical department of Shahid-Beheshti University of medical sciences. Patients were between 18 to 42 years old with an average of 28 years. To diagnose the problem tooth, a complete history along with clinical examination and radiographic image were procured. The patients were separated into 3 groups: group 1: control group (placebo), group 2: single dose & group 3: multi dose. Each groups contained 25 patients. After ordering the dexamethasone along with the placebos, we evaluated the level of effectiveness of each drugs on the patients pain, swelling and trismus after surgery with the use of the repeated measurement ANOVA test. The average level of pain present in each group (multi dose – single dose – control group) was evaluated. The results also showed that there was no significant different between the 3 group. The results also showed no significant different between the 3 groups in comparing the severity of trismus after evaluating the amount of swelling in each group, the results showed that the inflammation in the multi-dose group was reduced much sooner and faster compared to the other group. Results of this study indicated that, in compare to placebo, both regime of using dexamethasone were effective on reducing side effect of third mandibular molar surgery. However, after 48 hours, swelling in using multi dose dexamethasone was more than single-dose dexamethasone.

**Keywords:** Mandibular Third Molar Surgery, Dexamethasone Pills, Pain, Maximum Opening Of Mouth, Inflammation

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### INTRODUCTION

Extracting mandibular third molars is a prevalent surgeries related to mouth area. 90% of people suffer from impacted wisdom tooth and 33% have

at least one impacted wisdom tooth [1]. Genetic and environmental factors are considered as reasons of impaction [2]. Most mandibular third molars in mandible with common symptoms of pain and infection need surgery. One other issue is possible risk of infection center may put pressure on adjacent teeth and create cyst and tumor [3].

There are different methods for controlling post-surgical pain and swelling including consumption of anti-inflammatory drugs during and after surgery. Among these methods, local anesthesia by long-term effect, glucocorticoids and nonsteroidal anti-inflammatory drugs are used as methods [4].

It has been several decades that surgeons prescribe corticosteroids before or after third molar surgery for reducing inflammation and post-surgical side-effects. For controlling inflammation and trismus, using steroid anti-inflammatory drugs has better effect than anti-steroid anti-inflammatory drugs [5]. In spite of positive effects of corticosteroids, they may have some side effects including restraining hypothalamus-Adrenal axis, developing cushing's syndrome, cataract, glaucoma, increased blood pressure, muscular dystrophy, osteoporosis, mood change and psychosis, delicate skin, wounds healing delay, reducing resistance to infection, activation of *peptic ulcer* and diabetes [14].

Methods of minimizing side-effects are: local use of the drug, reducing dosage to every other day and reducing dosage to just a short time after healing. Activity of *hypothalamus-Adrenal axis* is decreased *when treatment is performed by Glucocorticosteroids* in long term or when high pharmacologic amount is used or both. So preventing this side effect, cautious aspects and contra indications need to be regarded as main issues [6].

Dexamethasone is one type of corticosteroid. Different doses of dexamethasone are widely used in dentistry for decreasing post-surgical pain and swelling. Dexamethasone has considerable effects on decreasing pain, edema and trismus after surgery. Stress of impacted third molar surgery is alleviated by receiving artificial steroid at the cellular level in order to prevent all adrenal gland reactions and anti-inflammatory effects. Dexamethasone has been effective on reducing

injuries caused by pressure or adema for 24 hours after surgery of mandible third molar [7].

Dexamethasone destroys immune system by reducing activity and volume of lymphatic system, by lymphocytopenia (mainly T lymphocytes), reducing passage of immune complexes from basic membranes and probably by inhibiting tissue reactions caused by antigen-antibody interference. Dexamethasone is an artificial *adrenocorticoide* with long-term mechanism effect, low mineralocorticoids property and strong anti-inflammatory activity [8].

Dosage of dexamethasone pill is different in different treatments. Dosage of edible pills is 2-12 milligram a day. Duration of treatment depends on clinical response of patients. Immediately after recovery, the dosage needs to be minimized in order to retain its effects. The withdrawal of dexamethasone pill should be carried out gradually [8]. Edible and injectable dexamethasones have different dosages while edible type needs to be used in longer term because they have different impact on effects and side-effects. In spite of side-effects, corticosteroids are valuable drug if they are used appropriately. Different studies are performed to investigate influence of drugs on reducing side effects of mandibular third molar surgery [9].

In a prospective study, Chaudhary *et al.*, [3] investigated preventive effects of injected dexamethasone after wisdom tooth surgery on inflammation, pain and trismus. Based on their findings, after mandibular third molar surgery, there is significant difference between effect of 4mg injectable type and 8 mg edible type of dexamethasone on inflammation and trismus.

In another research by Noboa *et al.*, [8] in 2014, effects of two formulation of dexamethasone on complications of third molar surgery were studied. Results of research indicated that there was no significant difference during surgery. However, there was significant statistical difference between both groups in case of inflammation and kinetic limitation ( $P > 0.05$ ). Average pain intensity had significant difference based on visual analog scale.

Based on WHO in 2015, 2-4mg dexamethasone is anti-pain while similar to 1mg dexamethasone, 25 mg hydrocortisone has anti-inflammatory effect.

There are no reports about suppressing hormonal system by dexamethasone [10]. According to main clinical effects of corticosteroids on reducing pain, inflammation and trismus in mandibular third molar surgery in dental treatments and also considering side-effects of these drugs, there is high disagreement among researchers about how to use edible and injectable types, so This study aimed to show clinical effects of dexamethasone on side-effects of mandibular third molars surgery.

### MATERIALS AND METHODS

This study was performed by double blind randomized clinical trial method. Data were collected by clinical observations and questionnaires. Statistical population included patients who were referred to the surgical department of Shahid-Beheshti dental school. Collected data were analyzed by SPSS software 21th version. Repeated measure ANOVA test was used to evaluate effects of double-doses of dexamethasone, single dose and placebo. The evaluation hours were determined and significant level was regarded as  $P < 0.05$ . 75 patients, 18-42 years old (28 years old as an average) were selected who had no pain and inflammation or TMJ problem and no systematically problems and they did not use any drugs (specially anti-inflammatory steroid drugs for last months), and also they were ok for being prescribed by corticosteroids. Patients with latent mandibular third molar (vertical or mesioangular latency) were studied. They were divided into three groups including 25 patients in control group, 25 patients in single-dose group and 25 patients in multi dose group. Patients and researchers were not aware of the group they were belonged to. Groups were divided into three groups including A, B and C. and pills were put in envelopes. Each envelope contained 4 pills, each 2 envelopes were attached to each other and name of the group and time of consumption were mentioned on.

In Group A which was Multi dose group, both envelopes had 8 pills of 0.5mg dexamethasone. In Group B which was control group, both envelopes had 8 pills of 0.5mg dexamethasone.

In Group C which was single dose group, one envelop had 4 pills of 0.5mg dexamethasone before surgery and the envelope which meant to

be given after surgery had 4 pills of 0.5mg placebo.

So, MD(multi dose) group received 2 mg dexamethasone before surgery and 2 mg dexamethasone after surgery (4 mg dexamethasone), SD(single dose) group received 2 mg dexamethasone before surgery and 2 mg placebo after surgery (2 mg dexamethasone), and control group received 2 mg placebo before surgery and 2 mg placebo after surgery (no dexamethasone).

All patients were told to use 0.5 mg dexamethasone which helps alleviation of pain, inflammation and muscle spasm and trismus. It was also used in this way that the pre-surgical envelope was used 1 hour before surgery and the post-surgical envelope was used 6 hours after using the first one. To sum it up I need to mention that 90 samples were studied (30 patients in each group) due to possibility of non-cooperation of some patients during the study and via this population, final volume would not be less than 75 patients.

### RESULTS

Results indicated that 30 minutes, 6 hours, 12 hours and 24 hours after surgery, mean pain score was different in 3 groups while repeated measure ANOVA test showed that these differences were not statistically significant in 4 mentioned times.

**Table 1: Mean and std. Deviation of pain before and after surgery**

	Descriptive Statistics			
	group	Mean	Std. Deviation	N
1. Pain before	1	.00	.000	25
	2	.00	.000	25
	3	.00	.000	25
	Total	.00	.000	75
2. Pain 30min	1	.20	.577	25
	2	.12	.600	25
	3	.24	.723	25
	Total	.19	.630	75
3. Pain 6hr	1	7.72	2.227	25
	2	8.08	2.178	25
	3	8.04	2.189	25
	Total	7.95	2.174	75
4. Pain 12hr	1	9.16	1.375	25
	2	9.00	1.500	25
	3	9.32	1.249	25
	Total	9.16	1.366	75
5. Pain 24hr	1	4.48	1.896	25
	2	5.48	2.257	25
	3	4.36	1.497	25
	Total	4.77	1.949	75

In addition, average maximum mouth opening size was 40.75 before surgery and standard deviation was 3.259. The mean score was different in 48 hours and 1 week after surgery. Repeated measure ANOVA showed that these differences were statistically significant in the two under study periods (p<0.0001). Inflammation difference was also significant in 48 hours and 1 week after surgery (P<0.0001). Inflammation of

all conditions within 1 week was reduced rather than 48 hours after surgery. Finally, according to the statistical analysis of pain before and after surgery, there was no significant difference in the 3 groups and no significant difference was found between the groups at all calculated times. Results are indicated in table 1 and table 2 and in diagram 1.

**Table 2: Distribution indicators of pain before and after surgery in 3 groups and pairwise comparison**

Pairwise Comparisons							
Measure: MEASURE_1							
Pain	(I) group	(J) group	Mean Difference (I-J)	Std. Error	Sig. <sup>a</sup>	95% Confidence Interval for Difference <sup>a</sup>	
						Lower Bound	Upper Bound
1	1	2	.000	.065	1.000	-.160	.160
		3	-.080	.065	.674	-.240	.080
	2	1	.000	.065	1.000	-.160	.160
		3	-.080	.065	.674	-.240	.080
	3	1	.080	.065	.674	-.080	.240
		2	.080	.065	.674	-.080	.240
2	1	2	.080	.180	1.000	-.362	.522
		3	-.040	.180	1.000	-.482	.402
	2	1	-.080	.180	1.000	-.522	.362
		3	-.120	.180	1.000	-.562	.322
	3	1	.040	.180	1.000	-.402	.482
		2	.120	.180	1.000	-.322	.562
3	1	2	-.360	.622	1.000	-1.884	1.164
		3	-.320	.622	1.000	-1.844	1.204
	2	1	.360	.622	1.000	-1.164	1.884
		3	.040	.622	1.000	-1.484	1.564
	3	1	.320	.622	1.000	-1.204	1.844
		2	-.040	.622	1.000	-1.564	1.484
4	1	2	.160	.390	1.000	-.796	1.116
		3	-.160	.390	1.000	-1.116	.796
	2	1	-.160	.390	1.000	-1.116	.796
		3	-.320	.390	1.000	-1.276	.636
	3	1	.160	.390	1.000	-.796	1.116
		2	.320	.390	1.000	-.636	1.276
5	1	2	-1.000	.540	.204	-2.323	.323
		3	.120	.540	1.000	-1.203	1.443
	2	1	1.000	.540	.204	-.323	2.323
		3	1.120	.540	.125	-.203	2.443
	3	1	-.120	.540	1.000	-1.443	1.203
		2	-1.120	.540	.125	-2.443	.203

**Table 3: Mean and Std. Deviation of MMO in 3 groups**

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
1.MMO (before)	1	40.40	3.000	25
	2	41.24	3.395	25
	3	40.60	3.440	25
	Total	40.75	3.259	75
2.MMO 48hr	1	38.04	3.182	25
	2	32.76	3.045	25
	3	29.96	2.406	25
	Total	33.59	4.421	75
3.MMO 1week	1	39.68	3.185	25
	2	39.24	3.099	25
	3	37.40	4.518	25
	Total	38.77	3.744	75

Table 4: Distribution indicators of MMO in 3 groups and pairwise comparison

Pairwise Comparisons							
Measure: MEASURE_1							
MMO	(I) group	(J) group	Mean Difference (I-J)	Std. Error	Sig. <sup>b</sup>	95% Confidence Interval for Difference <sup>b</sup>	
						Lower Bound	Upper Bound
1	1	2	-.840	.929	1.000	-3.117	1.437
		3	-.200	.929	1.000	-2.477	2.077
	2	1	.840	.929	1.000	-1.437	3.117
		3	.640	.929	1.000	-1.637	2.917
	3	1	.200	.929	1.000	-2.077	2.477
		2	-.640	.929	1.000	-2.917	1.637
2	1	2	5.280*	.820	.000	3.271	7.289
		3	8.080*	.820	.000	6.071	10.089
	2	1	-5.280*	.820	.000	-7.289	-3.271
		3	2.800*	.820	.003	.791	4.809
	3	1	-8.080*	.820	.000	-10.089	-6.071
		2	-2.800*	.820	.003	-4.809	-.791
3	1	2	.440	1.035	1.000	-2.097	2.977
		3	2.280	1.035	.092	-.257	4.817
	2	1	-.440	1.035	1.000	-2.977	2.097
		3	1.840	1.035	.239	-.697	4.377
	3	1	-2.280	1.035	.092	-4.817	.257
		2	-1.840	1.035	.239	-4.377	.697

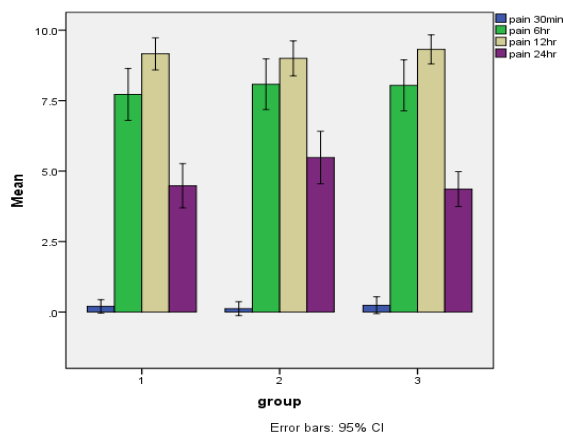


Diagram 1: Means of pain in different times after surgery

Maximum mouth opening size was not significantly different in three groups before surgery ( $P < 0.642$ ). However, within 48 hours after third molar surgery in the MD group, a significant difference was found between the three groups in the mean maximum opening of mouth, using one-way ANOVA ( $P < 0.0001$ ).

According to significant results of repeated measure ANOVA test, Tukey multiple comparison was used for pairwise comparing three groups. Accordingly, it was illustrated that difference between samples that used MD and SD dexamethasone, MD and control group ( $P < 0.0001$ ) and SD and control group ( $P < 0.003$ ) was significant. 1 week after latent third molar

surgery, it was observed that maximum mouth opening size had no significant difference in three groups and they were the same ( $P < 0.072$ ). Results of this section were indicated in table 3 and 4 and in diagram 2.

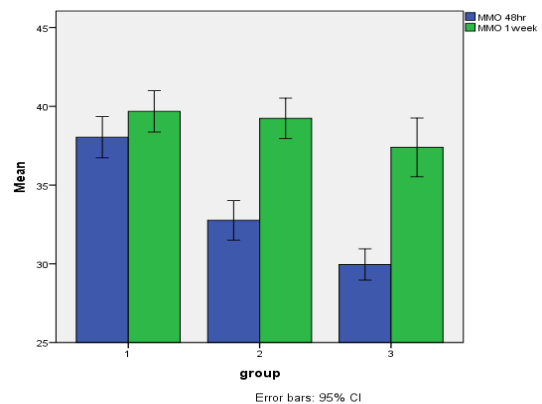


Diagram 2: Mean of MMO 48hr and 1 week after surgery

Before surgery, level of inflammation was not significantly different ( $P < 0.438$ ) while comparing inflammation by repeated measure ANOVA illustrated that after 48 hours, there was significant difference in groups ( $P < 0.0001$ ).

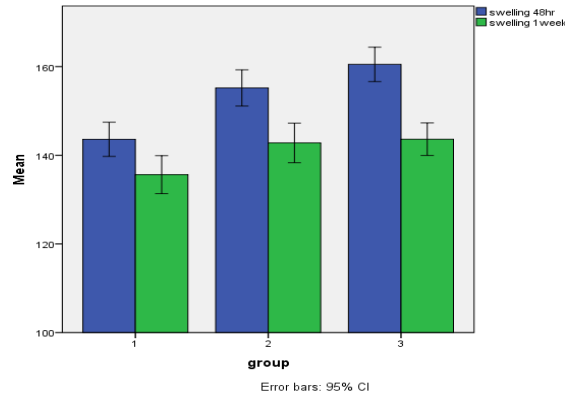
Pairwise comparing groups by Tukey test indicated that difference between MD and control, and SD and MD is significant ( $P < 0.0001$ ) but SD and control group did not show significant difference in inflammation 48 hours after surgery

( $P < 0.158$ ), while inflammation was significantly different in groups 1 week after surgery ( $P < 0.011$ ).

**Table 5: Mean and Std. Deviation of swelling before and after surgery in 3 groups**

Descriptive Statistics				
	Group	Mean	Std. Deviation	N
1.swelling before	1	135.16	9.852	25
	2	138.60	10.169	25
	3	136.68	8.158	25
	Total	136.81	9.413	75
2.swelling 48hr	1	143.60	9.332	25
	2	155.20	9.925	25
	3	160.52	9.386	25
	Total	153.11	11.804	75
3.swelling 1week	1	135.64	10.400	25
	2	142.80	10.797	25
	3	143.64	8.864	25
	Total	140.69	10.556	75

Pairwise comparing made clear that difference between SD and MD ( $P < 0.042$ ) and also MD and control group ( $P < 0.019$ ) was significant while there was no considerable difference between samples of SD and control group ( $P < 1.000$ ). Results are in table 5 and 6 and in diagram 3.



**Diagram 3: Mean of swelling 48 hr and 1 week after surgery**

**DISCUSSION**

Based on results, pain before surgery had no significant difference in three groups. According to statistical analysis and repeated measure ANOVA test, there was no significant difference in all determined hours of the study so multidoses and single dose of dexamethasone had no significant difference with control group in reducing pain at any time. Based on results of this study in 48

**Table 6: Distribution indicators of swelling before and after surgery in 3 groups before and after surgery and pairwise comparisons**

Pairwise Comparisons							
Measure: MEASURE_1							
Swelling	(I) group	(J) group	Mean Difference (I-J)	Std. Error	Sig. <sup>b</sup>	95% Confidence Interval for Difference <sup>b</sup>	
						Lower Bound	Upper Bound
1	1	2	-3.440	2.668	.604	-9.981	3.101
		3	-1.520	2.668	1.000	-8.061	5.021
	2	1	3.440	2.668	.604	-3.101	9.981
		3	1.920	2.668	1.000	-4.621	8.461
	3	1	1.520	2.668	1.000	-5.021	8.061
		2	-1.920	2.668	1.000	-8.461	4.621
2	1	2	-11.600*	2.701	.000	-18.222	-4.978
		3	-16.920*	2.701	.000	-23.542	-10.298
	2	1	11.600*	2.701	.000	4.978	18.222
		3	-5.320	2.701	.158	-11.942	1.302
	3	1	16.920*	2.701	.000	10.298	23.542
		2	5.320	2.701	.158	-1.302	11.942
3	1	2	-7.160*	2.844	.042	-14.131	-.189
		3	-8.000*	2.844	.019	-14.971	-1.029
	2	1	7.160*	2.844	.042	.189	14.131
		3	-.840	2.844	1.000	-7.811	6.131
	3	1	8.000*	2.844	.019	1.029	14.971
		2	.840	2.844	1.000	-6.131	7.811

Based on estimated marginal means

\*. The mean difference is significant at the .05 level.

b. Adjustment for multiple comparisons: Bonferroni.



hours after opening size was 38.04+3.182 in MD group, 32.76+3.045 in SD group and 29.96+2.406 in control group which they all indicated that there was significant difference in three groups and priority of MD over other two groups was clear ( $P < 0.0001$ ).

In pair wise comparison, the difference between MD and SD dexamethasone, MD and control group ( $P < 0.0001$ ) and SD and control group ( $P < 0.003$ ) was significant which proves dexamethasone use acted better than control group.

1 week after surgery of latent third molar, maximum mouth opening size was equal in three groups. Maximum mouth opening size for a patient using MD was 39.68+3.185, for patient using SD was 39.24+3.099 and for control group was 37.04+4.518 ( $P < 0.072$ ). Almost after certain time passing the surgery, there was no significant difference between the groups. However, the two dietary groups were relatively better than the control group taking placebo.

In studying inflammation in 48 hours after surgery, it was illustrated that level of inflammation of patients using MD was 143.6+9.332, for SD patients was 155.2+9.925 and for control group was 160.52+9.386. Comparing level of inflammation in 48 hours after surgery in three groups was performed by repeated measure ANOVA test and indicated that there was significant difference in three groups ( $P < 0.0001$ ).

Pairwise comparison of groups indicated that there was significant difference between MD and control group, and between SD and MD ( $P < 0.0001$ ) however, considering level of inflammation after 48 hours passing surgery, there was no significant difference between patients using SD and control group ( $P < 0.158$ ) which proved priority of dexamethasone effect over SD and control group, however SD had no significant difference with control group.

In studying inflammation 1 week after surgery, there was significant difference between groups (Repeated measure ANOVA). Level of inflammation in patients using MD was 135.64+10.14, in SD was 142.8+10.797 and in control group was 143.64+8.864 ( $P < 0.011$ ).

In pair wise comparison it was cleared that difference between SD and MD and also between MD and control group was significant ( $P < 0.019$ ) which there was no significant difference between patients using SD and control group ( $P < 1.000$ ). Results of 1 week after surgery indicated that in spite of long time after surgery, MD dexamethasone is better than other groups while SD had no significant difference with control group.

Bayat *et al.*, (2016) studied effects of injectable dexamethasone before latent mandibular wisdom tooth surgery on reducing pain, inflammation and trismus after surgery. They indicated that level of inflammation and maximum mouth opening size before latent mandibular wisdom tooth surgery was significantly difference in both groups that used injectable dexamethasone and control group in ( $P < 0.0001$ ). Results of both are similar despite they used injectable dexamethasone before surgery [11].

In one clinical study by Moore *et al.*, (2005) aimed to compare effect of dexamethasone and Rofecoxib on trismus after third molar surgery. They concluded that using of dexamethasone during surgery is an effective treatment in reducing post-surgical trismus. [12]. It showed that dexamethasone is effective on reducing third latent molar surgery side effects which is consistent with results of this study. In other study on assessing effect of muscular injected dexamethasone on Neurapraxia after third latent molar surgery, it was illustrated that Trismus and patients discomfort were affected by steroids, although the difference between control group and dexamethasone group was not statistically significant [13]. In this study, there was no difference in inflammation and daily pain in both groups which is not compatible with results of our study. Possible reasons of this difference are related to dosage of drug and numbers of injection.

In order to reduce side-effects of removing latent wisdom tooth, different methods of using dexamethasone are used including intravenous injection before and during surgery or oral consumption after surgery. In this study, group MD used 2mg edible dexamethasone one hour before surgery and 2 mg after that (6 hours after using first dose), SD group used 2mg edible dexamethasone before surgery and 2mg placebo

after that, and finally control group used 2mg placebo before surgery and 2 mg placebo after surgery. In order to provide identical experimental condition, it was tried to select surgeons who are able to remove latent wisdom tooth have highly similar methods and also chose mesioangular and vertical wisdom teeth. Most surgeries lasted 30 to 60 minutes and cutting was performed horizontally. Researchers had no information about patients and their groups.

In this study, patients became identical regarding different variables and possible intervening factors in three groups, so some specific entry criteria were applied. In order to avoid possible effect of mouth opening size on the results, before surgery, maximum size was measured and there was no significant difference between 3 groups. However, despite researchers' efforts, possibly, other intervening factors such as small or large oral cavities which cause less or more stretch during surgery should be taken into account. It was also attempted to perform surgeries in certain duration and procedure, with certain type of surgical teeth, and also identical systemic status of patients. By this method, interventional variables were controlled as much as possible.

All in all, in compare to SD and control group, level of inflammation was significantly higher after using MD dexamethasone.

### CONCLUSION

Results of the study illustrated that none of dexamethasone regime was helpful in reducing pain after latent third molar surgery. In addition both regimes that used dexamethasone were effective on reducing trismus and inflammation after latent third molar surgery. In compare to control group, both groups using dexamethasone had less trismus 48 hours after surgery and their mouths were opened more, but there was no significant difference 1 week after surgery. However, the rate of post-surgical inflammation in MD group was significantly higher than that of the SD group at both times.

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