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Research Article

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Comparison of Ondansetron and Ginger Effects on Pregnancy-Related Nausea and Vomiting

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Abstract

Nausea and vomiting are common complaints during pregnancy, observed in approximately 90% of pregnant women to varying degrees. Various herbal and chemical medicines are utilized to manage these symptoms. Ondansetron is the most prevalent chemical medication, and ginger is the most commonly consumed herbal remedy for managing nausea and vomiting during pregnancy nausea and vomiting during pregnancy (NVP). Given the trend toward herbal medicines, the researcher aimed to conduct a study comparing the effects of ondansetron and ginger (*Zingiber officinale*) on NVP in women attending the perinatal clinic.

The data collection tool was the Rhodes questionnaire. The triple-blind clinical trial was conducted on 40 pregnant women attending the perinatal clinic at Shohada ye Tajrish Hospital in Tehran, Iran (2021-2022). These women were suffering from mild to moderate NVP, as assessed by the Rhodes questionnaire. Participants were randomly divided into two groups: one group received ginger and the other received ondansetron. Each participant received a package labeled distinctly, containing 12 capsules in similar packaging. The medicine administration method involved taking one capsule every 12 hours for 4 days. Data analysis was performed using SPSS 23, employing independent t-tests and analysis of covariance (ANCOVA).

Before the intervention, there was no statistically significant difference between the two groups in terms of scores for nausea, vomiting, and retching. Post-intervention, no significant differences were observed between the two groups. However, intragroup changes showed a reduction in the levels of nausea, vomiting, and retching in both the ondansetron and ginger groups compared to before the intervention, which was statistically significant ($P< 0.001$ for both groups). Nonetheless, no significant statistical difference was observed between the changes in nausea ($P = 0.798$), vomiting ($P = 0.304$), and retching ($P = 0.270$) scores between the two groups.

Ginger, like ondansetron, may contribute to improving nausea, vomiting, and retching in pregnant women. Since pregnant women are often hesitant to use chemical medications due to concern about side effects, ginger may be an option for relieving NVP symptoms.

Keywords: Ondansetron; Ginger; *Zingiber officinale*; Nausea; Vomiting; Pregnancy.

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1. Introduction

Nausea and vomiting are common complaints during pregnancy, observed in approximately 90% of pregnant women to varying degrees [1]. Studies have shown that the prevalence of NVP is about 71.5% in Iran. The results of another study in 2021 reported that 28.30% of Iranian pregnant women had nausea, and 51.08% of them had vomiting [2, 3].

Typically commencing around the sixth week of pregnancy, these symptoms peak in week 12 and often resolve by the end of week 20 [4, 5]. Most women experience both nausea and vomiting, with a minority experiencing nausea, while isolated vomiting is rare [6]. While the exact causative agent remains unidentified, it appears to correlate with elevated levels of pregnancy hormones [4, 7, 8] in conjunction with biological, environmental, and psychological factors [4, 9].

Considering the variable prevalence of NVP, it presents significant challenges for pregnant women to endure [10]. It exerts negative impacts on women's quality of life, leading to fetal outcomes, potential birth of Small for Gestational Age (SGA) infants, and premature labor [1]. A multitude of herbal and chemical medicines are employed to manage these symptoms. Ondansetron, a serotonin antagonist, has witnessed increased usage as a remedy for NVP [11]. Its use during pregnancy does not lead to increased major anomalies, spontaneous abortion, or fetal demise [12]. According to the FDA classification, it is considered a category B substance [13].

This medication is available in both injectable and oral tablet forms, with an oral dosage of 8 milligrams every 12 hours in the treatment of NVP [14, 15]. However, pregnant women often avoid using it due to side effect concerns of chemical medicines [16, 17].

Ginger (*Zingiber officinale* Roscoe), a primary plant utilized in treating NVP, motion sickness, and digestive discomfort [14, 18, 19], belongs to the Zingiberaceae family [14]. Ginger possesses numerous therapeutic properties, including its role as an anti-nausea and anti-vomiting agent [20, 21]. In Iran, ginger is taken as a spice, an anti-flatulent remedy for NVP, and for enhancing intelligence and memory. When used within medicinal limits, ginger does not cause significant side effects [22], and it is considered safe during pregnancy [23]. However, it may interact with cardiac, diabetic, and anticoagulant medications. The recommended daily dosage for improving NVP is a maximum of 1 gram per day [15, 20].

However, due to apprehensions about teratogenic effects, pregnant women are hesitant to use medications, especially chemical medicines. Considering advancements in herbal medicine and research indicating the efficacy of ginger in alleviating NVP [20], as well as the safety profile of ondansetron as a chemical medication in addressing this issue [12, 14], researchers have undertaken the study to compare the effects of ginger and ondansetron on NVP. This study aims to contribute to innovation in pregnancy healthcare by integrating herbal and pharmacological approaches, ultimately offering new, effective, and safer treatment strategies for managing nausea and vomiting during pregnancy.

2. Materials and Methods

2.1. Study Design and Procedures

This study was designed as a randomized, triple-blind clinical trial. After obtaining approval from the Research Deputy of Pharmaceutical Sciences Research Center of Shahid Beheshti University of Medical Sciences, Tehran, Iran, and receiving authorization from the Ethics Committee with the reference number IR.SBMU.RETECH.REC.1399.1009, the researcher conducted sampling at Shohadaye Tajrish Hospital. The study was officially registered in the Iranian Registry of Clinical Trials (IRCT) under the identifier 20210303050564N1(Registered on April 14, 2021). So, all ethical considerations, methods, and guidelines were in accordance with the RCT's study guidelines.

2.2. Participants and Eligibility Criteria

Inclusion criteria: Pregnant women between 6 and 16 weeks of gestation [4] who were experiencing mild to moderate nausea and vomiting, carrying singleton pregnancies, lacking known sensitivities to ginger and ondansetron (according to the individual's statements), absence of recognized underlying illnesses, no high-risk pregnancies, and not taking anticoagulant medications, voluntarily participated in the research.

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Exclusion criteria: Pregnant women who did not complete the forms properly, withdrew from the study for any reason during the research, used any anti-nausea medication except the study medicines, used the medication for less than 4 days, or experienced severe NVP during the study.

2.3. Intervention and Randomization

In this study, ondansetron powder was procured from the Tehran Chemi Company, and ginger root powder was obtained from the market in Tehran, 2021. Subsequently, identical capsules were prepared by one of us (F. M.) at the Pharmaceutical Sciences Research Center of Shahid Beheshti University of Medical Sciences, Tehran filling them with either ondansetron or ginger powder and coding them uniquely. Each capsule of ginger contained 500 milligrams of ginger root powder, while each ondansetron capsule contained 8 milligrams of its powder [15]. These capsules, each packaged in sets of 12 capsules, were distributed to the participants. "Notably, due to the triple-blind nature of the study", neither the researcher, research units, nor statisticians had any knowledge regarding the type of medication being administered. The dosage regimen involved taking one capsule every 12 hours for 4 days. It was explained to the participants, including the proper use of medications, that they should record their symptoms daily in the questionnaire table, and they were instructed to submit the questionnaire to the responsible midwife at the first prenatal visit.

The purpose and process of the research were explained to the participants, and written informed consent was obtained for participation in the study. Sampling in this study initially employed an easy non-probability method among available samples, then randomly allocated research units into two comparative groups consuming either ginger or ondansetron (simple randomization). The first participant was randomly selected and placed into the ondansetron group using a lottery system. Subsequently, the allocation alternated between the two groups; the next participant was assigned to the ginger group and so on. Data were collected between September 2021 and September 2022. Due to the critical circumstances of the COVID-19 pandemic, the number of referrals to the center was severely limited, ultimately resulting in 40 participants in the study. The samples were followed up on 4 days after complete consumption. They were compared both before and after the intervention within each group and between the two groups.

2.4. Data Collection and Statistical Analysis

Data Collection Instrument

The data collection instrument utilized in this study was the Rhodes questionnaire. Initially developed by Rhodes and colleagues (1983), "comprising 6 items, the questionnaire and its nausea and vomiting index form 2 (INV-2) expanded to 8 items based on multiple studies by Rhodes and colleagues (1986)". This questionnaire consists of 3 subscales and 8 items (1- In the last 12 hours, I threw up __ times, 2-In the last 12 hours, from retching and dry heaves, I felt __ distress, 3- In the last 12 hours, from vomiting or throwing up, I have felt __ distress, 4-In the last 12 hours, I have felt nauseated or sick to my stomach, 5-In the last 12 hours, because of nausea/sickness, I have felt __ distress, 6-In the last 12 hours, each time I threw up, I produced a __ amount, 7-In the last 12 hours, I have felt nauseated or sick to my stomach __ times, 8-In the last 12 hours, I have had periods of retching or dry heaves without bringing anything up __ times). Its validity and content reliability were confirmed in Korea through "Spearman correlation of 0.96 and Cronbach's alpha reliability ranging from 0.91 to 0.96" [24]. Furthermore, its validity and reliability in Iran were assessed using content validity and test-retest methods, confirming its reliability with a correlation coefficient of 0.8 [25]. The score range of this questionnaire is between 0 and 32, with higher scores indicating more severe nausea and vomiting.

Sample Size Calculation

The sample size was calculated based on findings from the study by Chitoma et al. [26], considering a mean and standard deviation for the first group as 2.2 ± 1.5, for the second group as 2.4 ± 1.3, a 30% dropout rate, a confidence level of 95%, and a power of 80%, and effect size 2.2 resulting in 23 individuals in each group (allocation ratio: 1.4).

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 * (\sigma_1{}^2 + \sigma_2{}^2)}{(d)^2}$$

$z_{0.975}$= 1.96 $z_{0.8}$= 0.84 d= 2.2

σ_1= 2. 2 σ_2= 2.4

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Statistical Analysis

Data analyzed by SPSS statistical software (version 23). Initially, the Shapiro-Wilk test was employed to assess the normality of variables, revealing a normal distribution for the research variables. Therefore, independent t-tests were utilized to compare the two groups before the intervention, while analysis of covariance (ANCOVA) was employed to compare the two groups after the intervention. Moreover, the assumptions of homogeneity of regression slope and variance were evaluated for the ANCOVA test, confirming their adherence at a significance level of 0.05. Additionally, paired t-tests were used to assess within-group changes.

3. Results and Discussion

Initially, 50 participants were enrolled and randomly assigned to one of the two groups. However, by the end of the study, 17 participants remained in the ondansetron group, while 23 participants remained in the ginger group (**Figure 1**).

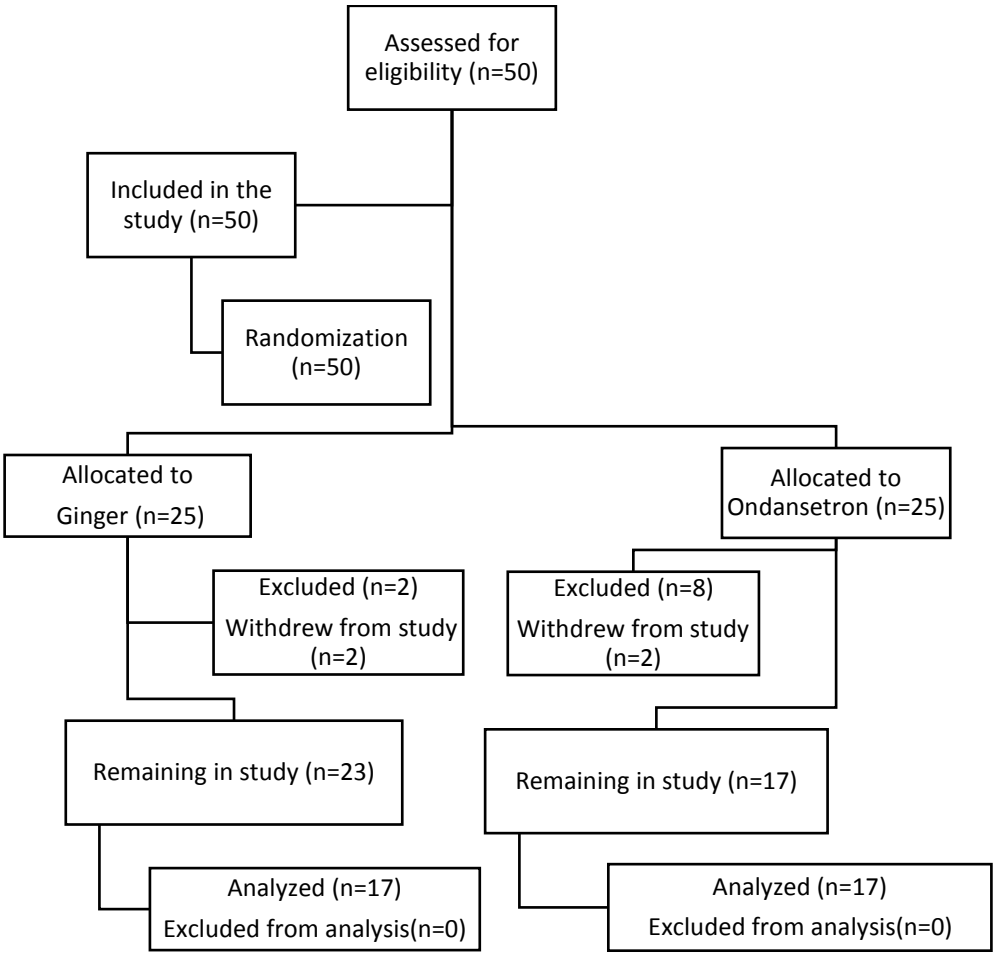


Figure 1. CONSORT diagram of study

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The pregnant women in both groups were homogeneous in terms of their demographic characteristics (**Table 1**).

According to the independent t-test results, no significant difference was observed in the nausea, vomiting, and retching scores between the ondansetron and ginger groups before the intervention (p = 0.690, p = 0.634, and p = 0.206, respectively). Similarly, after the intervention, based on the ANCOVA results, no significant difference was found between the two groups (p = 0.944, p=0.334, and p=0.677, respectively). However, within-group changes indicated a reduction in nausea, vomiting, and retching levels among pregnant women in both the ondansetron and ginger groups after the intervention compared to before the intervention. The paired t-test demonstrated a significant difference in these changes (**Table 2**). Additionally, based on the independent t-test, no significant difference was found between the changes in nausea, vomiting, and retching scores among pregnant women in the two groups (p = 0.798, p=0.304, and p=0.270, respectively).

Table 1. Demographic Characteristics of Participants.

Demographic Characteristics	Level	Ondansetron (n=17)		Ginger(n= 23)		Test Statistic	Significance Level
		Number	Percentage	Number	Percentage		
Education Level	Below Diploma	5	29.4	5	21.7	0.86 $X^2(2)=$	P=0.653
	Diploma and Above	7	41.2	8	34.8		
	Bachelor's	5	29.4	10	43.5		
***Occupation**	Homemaker	14	82.4	20	87	-	P=1
	Employed	3	17.6	3	13		
Gravidity	1	11	64.7	14	60.9	2.97 $X^2(2)=$	P=0.226
	2	2	11.8	7	30.4		
	≥3	4	23.5	2	8.7		
Number of deliveries	Zero	12	70.6	14	60.9	3.95 $X^2(2)=$	P=0.139
	1	2	11.8	8	34.8		
	≥2	3	17.6	1	4.3		
History of Nausea in Previous *Pregnancy	No	13	76.5	18	78.3	-	P=1
	Yes	4	23.5	5	21.7		
Type of Treatment	None	13	76.5	20	87	0.81 $X^2(2)=$	P=0.669
	Herbal	1	5.9	1	4.3		
	Chemical	3	17.6	2	8.7		
Effect of Previous Treatment	No	13	76.5	20	87	-	P=0.432
	Yes	4	23.5	3	13		
Age (Years); (SD) Mean		27.59(5.71)		27.35(4.09)		T=0.16	P=0.877
Age at Marriage (Years); (SD) Mean		22.65(4.97)		23.17(3.85)		T=-0.38	P=0.807
Gestational Age at Onset of Nausea (Weeks); (SD) Mean		5.82(1.38)		5.52(1.67)		T=0.61	P=0.548
Body Mass Index; (SD) Mean		23.17(3.33)		24.63(3.07)		T=-1.42	P=0.836

*: Fisher's Exact Test χ: Chi-squared Test t: Independent t-test, SD: Standard Deviation

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Table 2. Mean and Standard Deviation of Pregnant Women's Nausea, Vomiting, and Retching Scores before and after Intervention in the Ondansetron and Ginger Groups.

	Group	Prior to Intervention Standard Deviation ± Mean	After Intervention Standard Deviation ± Mean	Mean Change	Within-Group Estimated Statistics
Nausea Scores	Ondansetron	5.17 ± 1.59	1.76 ± 1.34	-3.41	t^{*} = 14.02, P<0.001
	Ginger	5.39 ± 1.72	1.86 ± 1.68	-3.52	t^{*} = 11.02, P<0.001
	Between- Group Estimate	t^{**} =-0.41 p=0.690	F^{***} =0.01 P=0.944 0.001= Effect Size	t^{**} =-0.26 , P=0.798	
Vomiting Scores	Ondansetron	4.70 ±2.05	1.41 ± 1.54	-3.29	t^{*} =8.24, P<0.001
	Ginger	4.34 ±2.51	1.56 ± 1.72	-2.78	t^{*} =9.24, P<0.001
	Between-Group Estimate	t^{**} =0.48, P=0.634	F^{***} = 0.96 , P=0.334 0.025= Effect Size	t^{**} =1.04, P=0.304	
Retching Score	Ondansetron	2.94 ± 1.34	1.17 ± 1.01	-1.76	t^{*} =6.67, P<0.001
	Ginger	3.47 ± 1.27	1.34 ± 1.11	-2.13	t^{*} =10.56, P<0.001
	Between-Group Estimate	t^{**} = −1.29 , P= 0.206	F^{***} =0.18 , P=0.677 Effect Size= 0.005	= −1.12 , P=0.270	

Paired t-test, ** Independent t-test, *** Analysis of Covariance.

Based on the results of independent t-tests, there was no significant difference in the total scores of nausea, vomiting, and retching between the Ondansetron and Ginger groups before the intervention (p = 0.792). Similarly, after the intervention, according to the results of the covariance analysis, no significant difference was observed between the two groups (p = 0.823). However, within-group changes indicated that, following the intervention, the total score of nausea, vomiting, and retching in both the Ondansetron and Ginger groups decreased by 8.47 and 8.43 units, respectively, compared to pre-intervention. The paired t-test indicated that this difference was statistically significant (**Table 3**). Finally, the independent t-test showed no significant difference in the total score changes between the two groups (p = 0.971).

Discussion

The results of this study indicate that ginger capsules are just as effective as ondansetron in reducing NVP. Several double-blind clinical trials investigating the impact of ginger capsules on NVP have reported that ginger effectively reduced the severity of maternal nausea [21, 27, 28]. Studies have also shown that ginger leads to significant improvements in the duration, intensity, and frequency of nausea and vomiting compared to a placebo [28, 29]. One study comparing ginger to metoclopramide [30] found significant differences in favor of ginger when it came to reducing nausea severity and vomiting frequency.

Table 3. Mean and Standard Deviation of Scores for Total Nausea, Vomiting, and Retching in Pregnant Women Studied Before and After Intervention in the Ondansetron and Ginger Groups.

Group	Prior to Intervention Standard Deviation ± Mean	After Intervention Standard Deviation ± Mean	Mean Change	Within-Group Estimated Statistics
Ondansetron	12.82± 4.26	4.35 ±3.60	-8.47	t^{*} =11.55, P<0.001
Ginger	13.21 ± 4.89	4.78 ± 3.99	-8.43	t^{*} = 12.98, P<0.001
Between-Group Estimate	t^{**} = −0.27, P= 0.792	F^{***} =0.05 P=0.823 Effect Size= 0.001	t^{**} =0.04, P=0.971	

Paired t-test, ** Independent t-test, *** Analysis of Covariance.

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This may be due to the fact that ginger and metoclopramide work in different ways—ginger targets inflammation and nausea pathways, while metoclopramide focuses on dopamine receptors and gut motility. Therefore, it is possible that ginger is more effective for certain people depending on how their bodies respond.

There is also research comparing ginger with vitamin B_6 for treating NVP, which shows both have positive effects, but the ginger group seemed to experience more noticeable symptom reduction [26, 31]. These differences could be due to variations in dosage or individual responses to treatment. Our findings align with these studies, highlighting the positive impact of ginger on NVP.

In general, the results suggest that ginger is an effective, natural option for treating NVP, and in some cases, it might even work better than medications like metoclopramide or vitamin B_6 [32, 33]. However, the differences between studies—whether it's the dosage, study design, or patient characteristics—play a big role in why we see some variations in the results.

Our study found that ginger capsules are just as effective as ondansetron in reducing nausea and vomiting during pregnancy (NVP), which lines up with other studies. For example, a 2023 study comparing ginger tablets with ondansetron showed similar results, with ginger being just as effective in cutting down the frequency and severity of NVP [34]. This backs up our own findings and suggests that ginger could be a strong alternative to ondansetron.

That said, there are some differences in results when comparing other studies. One study comparing ondansetron and metoclopramide found no major difference in how both medicines reduced nausea, although ondansetron did significantly reduce vomiting episodes [32]. The reasons for this could be the different ways these medications work—ondansetron blocks serotonin receptors, while metoclopramide affects dopamine and gut motility. Ginger, on the other hand, works through anti-inflammatory and anti-nausea pathways, which might explain why it shows different results in different studies or populations.

Another study looked at combining ginger with ondansetron for post-surgical nausea and found that the combination worked better than ondansetron alone [33]. This suggests that ginger might enhance the effects of traditional treatments when used together, a factor we didn't explore in our research, which focused on ginger alone as a potential alternative to ondansetron.

These differences highlight how important it is to consider treatment details like dosage, patient population, and how each treatment works when comparing results. While our study supports ginger as a promising treatment for NVP, combining it with other medications could lead to even better results, as seen in some of the studies.

In the present study, pregnant mothers in both groups did not report any specific side effects from the medicine usage. A study titled "Safety of Ondansetron for NVP" found no statistically significant difference between the ondansetron-consuming group and other groups. Therefore, this medicine does not increase the risk of major abnormalities [35]. Another review study stated that ginger, as a prominent medication, effectively reduces the severity of nausea and vomiting without significant adverse effects on pregnancy outcomes. There were no reports of side effects during ginger treatment throughout pregnancy [36], which is consistent with the present study's findings. However, the results of another study showed that despite ginger being an effective herbal remedy for NVP, it has contraindications, precautions, and potential side effects, the most notable of which is its anticoagulant properties [37]. These differences play a big role in variations in the dosage used, the population studied, or the length of treatment. Therefore, it seems that both ginger and ondansetron could be effective in alleviating NVP.

The similarity in findings about ondansetron safety between our study and others suggests that both likely involved healthy pregnant women with no complicating conditions, which could explain the lack of side effects. As for ginger, the differences in results might come down to factors like dosage or the health of the participants. The study mentioning side effects might have used higher doses or included women with underlying conditions, making them more sensitive to ginger's anticoagulant effects. On the other hand, your study probably used a lower, safer dose or focused on women without these additional risks.

4. Conclusion

Based on the study, it appears that the consumption of ginger, similar to ondansetron, could be effective in

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reducing nausea, vomiting, and queasiness in pregnant women. As modern medicine is increasingly leaning toward the use of herbal remedies, suggesting the use of ginger for improving NVP seems plausible. However, caution should be exercised regarding the daily dosage of ginger during pregnancy.

Ethics Declarations:

The material in the manuscript has been acquired according to modern ethical standards and has been approved by the legally appropriate ethical committee (IR.SBMU.RETECH.REC.1399.1009).

We have obtained written informed consent from all participants.

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This study has been approved by the Research Deputy of Pharmaceutical Sciences Research Center of Shahid Beheshti University of Medical Sciences, Tehran, Iran. Hereby, the authors would like to appreciate all participants, the Pharmaceutical Sciences Research Center of Shahid Beheshti University of Medical Sciences, and the research deputy of Shohadaye Tajrish Hospital.

Conflict of interest

All authors have no competing interests. Author (A) declares that she has no conflict of interest. Author (B) declares that he has no conflict of interest. The author (C) declares that there is no conflict of interest. The author (D) declares that he has no conflict of interest. The author (E) declares that he has no conflict of interest.

Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Authors Contributions

All authors wrote the main manuscript text, A and E helped in sampling and data collection, A and C prepared tables, Data analysis was performed by A and B, and all authors reviewed the manuscript.

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Using artificial intelligence chatbots

There was no use of artificial intelligence in the making of this article.

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