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Comparing the maternal and neonatal outcomes in vaccinated and unvaccinated pregnant women against COVID-19: a retrospective cohort study

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Abstract

Background Following the emergence of COVID-19 disease, and considering the limited number of studies regarding vaccination among pregnant women, as well as the differences between the vaccine administered in Iran and those used in other countries, this study aimed to compare maternal and neonatal outcomes in vaccinated and unvaccinated women against COVID-19 disease.

Methods This retrospective cohort study was conducted at the comprehensive healthcare centers of Rafsanjan city. Initially, the contact information of expectant mothers who were pregnant between June 22, 2021, and December 22, 2021, was obtained through Iran's integrated healthcare system (Sib). Subsequently, the required information was collected via a checklist during phone interviews. Out of 969 pregnant women, after applying the inclusion and exclusion criteria, 610 subjects were included in the study. Among these, 330 were unvaccinated, while the remaining participants had received the inactivated COVID-19 vaccine prior to or during pregnancy. Maternal and neonatal outcomes were compared between vaccinated and unvaccinated women. Data analysis was performed using SPSS version 26, employing one-way analysis of variance (ANOVA), Tukey's multiple comparison test, Fisher's exact test, Chi-square test, and multiple logistic regression.

Results The findings indicated that vaccination against COVID-19 in pregnant women significantly increased the risk of neonatal jaundice ($P < 0.05$). Conversely, the miscarriage rate among these women was significantly lower ($P < 0.05$). No adverse outcomes were observed including hypertensive disorders, gestational diabetes, maternal hospitalization, maternal COVID-19 infection, preterm labor, premature rupture of membranes, perinatal mortality, admission to the neonatal intensive care unit, and low birth weight.

Conclusions COVID-19 Vaccination is recommended for pregnant women to mitigate adverse neonatal and maternal outcomes.

Keywords COVID-19 vaccination, Neonatal and maternal outcomes, Miscarriage, Neonatal jaundice, Pregnant women

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Background

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2)[1] is a type of coronavirus capable of causing pandemics that belongs to the beta-coronavirus species, alongside its counterparts Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) [1]. Pregnancy represents a critical period in a woman's life [2, 3], during which physiological changes significantly impact the immune system. The reduction in lung capacity makes pregnant women more vulnerable to respiratory infections, including pneumonia, which inherently increases the risk of lung infections associated with SARS-CoV-2. As the immune response is compromised, pregnant women are at a heightened risk for contracting COVID-19 [1, 4–9]. Given that pregnant women have a greater susceptibility to severe manifestations of COVID-19 compared to non-pregnant women of childbearing age, they face a higher likelihood of requiring admission to ICU[2], undergoing invasive ventilation procedures (such as endotracheal intubation and ECMO[3]) and even experiencing mortality [10–12]. Research indicates that COVID-19 during pregnancy is linked to a heightened risk of pregnancy-related complications, including preeclampsia, preterm labor, cesarean section and stillbirth [10, 11, 13–19].

The medical management of COVID-19 during pregnancy faced significant challenges due to the presence of the fetus and placenta [1]. Additionally, pregnant women were often underrepresented in the populations participating in vaccine trials [20]. In light of the absence of an effective and safe treatment for COVID-19, vaccines emerged as the primary hope for controlling the pandemic [21]. However, due to limited data on the implications of vaccination for pregnant women, this population was initially excluded from COVID-19 vaccination efforts [20]. The urgency of the COVID-19 pandemic necessitated the development of vaccination strategies specifically tailored for pregnant women and their infants, as both groups were at increased risk for severe disease [12, 22, 23]. Given the heightened vulnerability of pregnant women, COVID-19 infection was associated with a substantial risk of mortality in this population, prompting their inclusion in vaccination programs [24]. As of July 2021, there were 184 COVID-19 vaccines in the preclinical development stage, 105 vaccines in clinical trials, and 18 vaccines that had received emergency use authorization from at least one regulatory body [25]. The majority of these vaccines were protein subunit vaccines, commonly referred to as peptide vaccines. Additionally, mRNA vaccines, inactivated viral vaccines, non-replicating viral vector vaccines, DNA vaccines, and recombinant protein vaccines gained prominence during this period. Inactivated vaccines consist of viruses whose genetic material has been rendered non-infectious through processes such as heat, chemical treatment, or radiation, which prevents them from infecting cells or replicating. However, they are still capable of eliciting an immune response. The Sinopharm vaccine employs this technology [25, 26]. Inactivated virus vaccines, including Sinopharm, represent some of the most commonly used COVID-19 vaccines globally [26]. A study conducted in Scotland revealed that the incidence of COVID-19 infections during pregnancy parallels trends seen in women of childbearing age. Notably, the highest rate of COVID-19 infection was recorded among pregnant women compared to their older counterparts and younger women in disadvantaged areas. An analysis of three vaccines: Pfizer, Moderna, and AstraZeneca, indicated that all perinatal fatalities occurred in unvaccinated women diagnosed with COVID-19 [10]. A separate study in Israel assessed the outcomes associated with the Pfizer vaccine. This vaccine was not linked to negative maternal or neonatal outcomes, but it was found to reduce the risk of meconium staining of amniotic fluid in the vaccinated group [27]. A systematic review aimed at evaluating perinatal outcomes following COVID-19 vaccination found no increase in adverse outcomes, including miscarriage, preterm labor, maternal mortality, ICU admissions, low birth weight, or NICU admissions, and noted a significant decline in the rate of stillbirths [28].

The COVID-19 vaccination program for pregnant women in Iran commenced in August 2021, utilizing the Sinopharm vaccine. Initially, the program targeted pregnant women over 18 years of age and beyond 12 weeks of gestation, with vaccination prioritized for those at 28 weeks of gestation and later. Revised guidelines issued in December 2021 indicated that there were no contraindications for administering vaccines during the first 12 weeks of pregnancy. Furthermore, individuals who received their first dose of the AstraZeneca vaccine before or at the onset of an unplanned pregnancy were allowed to receive their second dose [29]. While numerous studies have investigated the impact of COVID-19 on pregnancy outcomes [1, 2, 30–32], there is a paucity of research examining the effects of the vaccine on maternal and neonatal outcomes. Given the lack of accurate and comprehensive data, as well as the scarcity of Iranian studies in this area, alongside the different vaccines utilized in international studies assessing the vaccination of pregnant women against COVID-19 [particularly those measuring the Pfizer and Moderna vaccines, which are

[1] The virus that causes the disease known as coronavirus disease 2019.

[2] Intensive Care Unit.

[3] Extra-corporal membrane oxygenation.

based on mRNA[4] technology], this study was conducted to compare maternal and neonatal outcomes among vaccinated and unvaccinated pregnant women, aiming to clarify existing uncertainties.

Implementation

This study was a retrospective cohort investigation conducted in 2023 in Rafsanjan City, documented under the ethics code IR.RUMS.REC.1402.064, following approval by the Research Committee of Rafsanjan University of Medical Sciences.

Upon presenting a letter of introduction to the researcher, information regarding contact details, occupation, educational background, vaccination history against COVID-19, Iranian or non-Iranian status, and LMP[5] was extracted over a six-month period (22 June 2021–22 December 2021) through the Integrated Health System of Iran (Sib) in Rafsanjan. The initial number of participants in this sampling was 969 participants (Fig. 1). During a phone call with the participants, the research team explicated the study's purpose, assured confidentiality concerning the information provided,

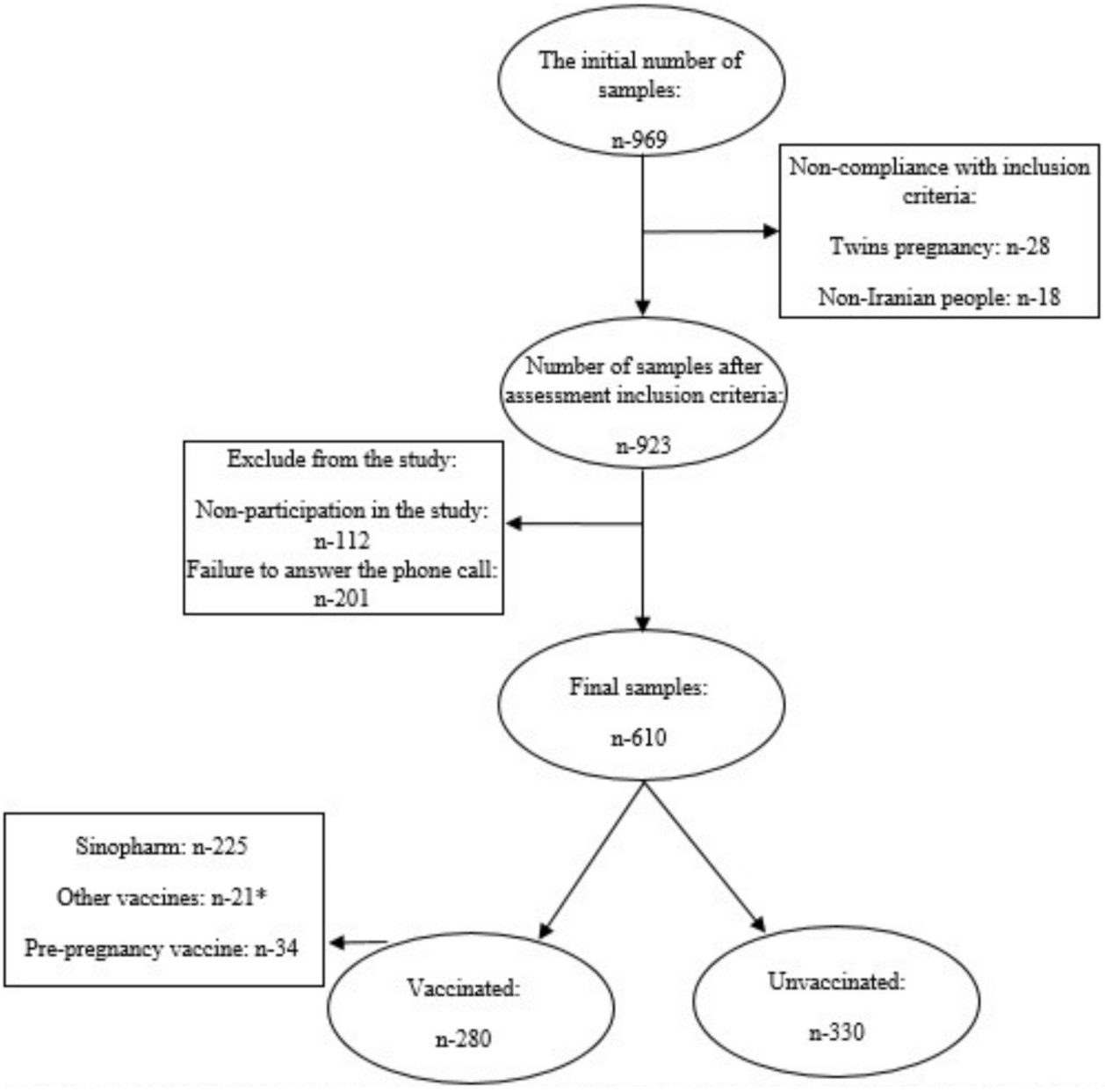

Fig. 1 Diagram of the comparative study of maternal and neonatal outcomes in vaccinated and unvaccinated pregnant women against COVID-19

[4] Messenger RNA.

[5] Last menstrual period.

verified eligibility criteria, and secured informed consent. Subsequently, women were administered a series of checklist questions. Informed consent to participate in this study was obtained from all participants utilizing a predefined form approved by the Ethics Committee of Rafsanjan University of Medical Sciences. The consent form confirmed that participants were informed their personal information would remain confidential with the researcher, and it was clarified that results would be reported in aggregate form, with no individual identifiers, in the final manuscript.

Participants who did not respond to the initial phone call were sent an SMS containing an introduction to the researcher and the purpose of the study, followed by a second attempt to reach them phone call. If the participant did not answer the phone call, they were excluded from the study. Given the challenges associated with accurately recalling the date of vaccination or the specific type of vaccine received during or around pregnancy, these details were corroborated through the Sib system. Furthermore, in cases where the LMP did not correspond with the gestational age reported by the mother at delivery, the first recorded ultrasound of the pregnant individual was reviewed in the system for confirmation. Ultimately, upon completion of the calls, we obtained a sample of 610 participants with complete data.

Subsequently, the pregnant women were categorized into two groups: vaccinated and unvaccinated. Each subject within both groups was assigned a unique identification number, and the final data for each individual was entered into the SPSS version 26. Maternal and neonatal outcomes (including hypertensive disorders, gestational diabetes mellitus, maternal hospitalization, maternal COVID-19 infection, premature rupture of membranes, preterm labor, cesarean section, miscarriage, maternal mortality, stillbirth, perinatal mortality, low birth weight, neonatal jaundice, NICU admission, and sepsis) were then compared between the two groups, taking into account the type, number of vaccine doses, and timing of vaccination during pregnancy.

One-way ANOVA was employed to investigate the relationship between age and vaccination type, while Fisher's exact test was used to examine the association between occupation, education level, and vaccination type. To assess the relationship between vaccination type, number of vaccine doses, timing of vaccination, and maternal outcomes (including cesarean section, miscarriage, maternal hospitalization, maternal COVID-19 infection, hypertensive disorders, gestational diabetes mellitus, preterm labor, and premature rupture of membranes) as well as neonatal outcomes (such as perinatal mortality, NICU admission, neonatal jaundice, and low birth weight), multiple logistic regression analysis was conducted, adjusting for the effects of confounding variables. The results of the logistic regression analysis were presented as odds ratios (OR) with 95% confidence intervals, and a P-value of less than 0.05 was considered statistically significant.

Results

In the present study, which included 610 mothers, the mean age of the pregnant women was 29.99 ± 5.47 years, with an age range of 16 to 44 years. The educational level of the majority of pregnant women (52.6%) exceeded a higher than diploma; 89 pregnant women (14.6%) had below diploma, 171 pregnant women (28%) held a diploma, and 29 pregnant women (4.8%) had not reported their educational status. Additionally, 427 pregnant women (70%) were housewives, 77 pregnant women (12.6%) were employed, and the employment status of 106 pregnant women (17.4%) was not registered (Table 1).

The results indicated that more than half of the pregnant women attending the comprehensive health centers of Rafsanjan in 2021 had not received any vaccine. Among those vaccinated, the majority received the Sinopharm vaccine. Less than one-third of the women studied had received at least one dose of the vaccine during

Table 1 The relationship between the demographic characteristics of age, occupation, as well as education level and the number of vaccination doses during pregnancy in pregnant women referring to comprehensive health service centers (n-610)

The number of vaccine Variable	Unvaccinated** (*n*-364)	One dose (*n*-91)	Two dose (*n*-139)	Three dose (*n*-16)	Statistical test statistic	*P* value
Age (years)	29.26 ± 5.34[a]	30.66 ± 5.49 [a]	30.91 ± 5.41 [a]	34.94 ± 5.20 [b]	8.593	< 0.001*
Job	258 (70.9)	62 (68.1)	94 (67.6)	13 (81.3)	10.141	0.119[†]
Housewife	41 (11.3)	8 (8.8)	26 (18.7)	2 (12.5)		
Employed	65 (17.9)	21 (23.1)	19 (13.7)	1 (6.3)		
Not registered						
Education level	45 (12.4)	18 (19.8)	23 (16.5)	3 (18.8)	9.414	0.400[††]
Under diploma	107 (29.4)	27 (29.7)	33 (23.7)	4 (25.0)		
Diploma	192 (52.7)	41 (45.1)	80 (57.6)	8 (50.0)		
Above diploma	20 (5.5)	5 (5.5)	3 (2.2)	1 (6.3)		
Not registered						

The data in the table are reported as "standard deviation ± mean" for quantitative variables and as "(percentage) number" for qualitative variables. * One-way analysis of variance, ** includes unvaccinated and pre-pregnancy vaccine. † Chi-square test, †† Fisher's exact test

the first trimester of pregnancy. Of those admitted to the hospital, which constituted only 15% of the total number of pregnant women, 2% were hospitalized due to COVID-19 infection. The most common neonatal outcome observed in more than half of the deliveries was neonatal jaundice. Perinatal mortality was observed in fewer than 7% cases. Importantly, there were no instances of maternal death reported, and only one case of neonatal sepsis was observed.

As reported in Table 1, Tukey's multiple comparisons test indicated that the mean age of women who received three doses of the vaccine during pregnancy was significantly higher than the mean age of pregnant women in other groups ($P<0.05$). The groups represented with different English letters in Table 1 demonstrate a statistically significant difference in mean age ($P<0.05$).

Based on the study results, regarding maternal outcomes, there was no statistically significant relationship between vaccination type, number of vaccine doses, timing of vaccination, and the occurrence of hypertensive disorders, preterm labor, cesarean section, maternal COVID-19 infection, gestational diabetes mellitus, premature rupture of membranes and maternal hospitalization ($P>0.05$) (The tables are available in the supplementary file).

According to Table 2, pregnant women who received the Sinopharm vaccine had a significantly lower likelihood of experiencing miscarriage compared to those who did not receive the vaccine. Additionally, pregnant women who received two doses of the vaccine during pregnancy exhibited a significantly lower risk of miscarriage compared to unvaccinated women. Furthermore, pregnant women who received at least one dose of the vaccine during the second trimester of pregnancy had a significantly reduced risk of miscarriage compared to unvaccinated pregnant women.

In summary, receiving the Sinopharm vaccine during pregnancy, receiving two doses of the vaccine during pregnancy, and receiving at least one dose in the second trimester of pregnancy were all associated with a significantly lower chance of miscarriage ($P<0.05$).

Regarding neonatal outcomes, no statistically significant relationship was observed between vaccination type, number of vaccine doses, timing of vaccination, and perinatal mortality, low birth weight, or admission to the NICU ($P>0.05$) (The tables are available in the supplementary file).

According to Table 3, pregnant women who received the Sinopharm vaccine had a significantly higher likelihood of experiencing neonatal jaundice compared to those who did not receive the vaccine. Additionally, women who received two doses of the vaccine during pregnancy exhibited a significantly higher chance of neonatal jaundice compared to unvaccinated pregnant women. Furthermore, pregnant women who received at least one dose of the vaccine during the second or third trimester of pregnancy had a significantly increased likelihood of neonatal jaundice compared to those who did not receive the vaccine.

In summary, receiving the Sinopharm vaccine during pregnancy, receiving two doses of the vaccine during pregnancy, receiving at least one dose in the second trimester, and receiving at least one dose in the third trimester were all associated with a significantly higher chance of neonatal jaundice ($P<0.05$).

Considering the pregnant women who referred to comprehensive health service centers in Rafsanjan in 2021 ($n=610$), there were no cases of "maternal death" and only one instance of "neonatal sepsis" occurred. Therefore, it was not possible to examine the relationship between vaccination type, number of vaccine doses,

Table 2 The relationship between the type of vaccination, the number of vaccine doses, as well as the time of vaccination and miscarriage in pregnant women referring to comprehensive health service centers (n-610)

Miscarriage Variable		Not occurred	occurred	Odds ratio* (confidence interval 95%)	*P* value
vaccination type	Unvaccinated (n-330)	291 (88.8)	39 (11.8)	1.000	0.003
	Sinopharm (n-225)	213 (94.7)	12 (5.3)	0.376 (0.188–0.750)	
	Other vaccines (n-21)	20 (95.2)	4 (4.8)	0.320 (0.041–2.491)	
	Pre-pregnancy vaccine (n-34)	27 (79.4)	7 (20.6)	2.266 (0.899–5.712)	
number of vaccine doses during pregnancy	Unvaccinated (n-364)	318 (87.4)	46 (12.6)	1.000	0.019
	One dose (n-91)	79 (86.8)	12 (13.2)	1.022 (0.505–2.070)	
	Two dose (n-139)	138 (99.3)	1 (0.7)	0.041 (0.005–0.301)	
	Three dose (n-16)	16 (100)	0	-	
timing of vaccination during pregnancy	Unvaccinated (n-364)	318 (87.4)	46 (12.6)	1.000	0.031
	At least one dose in the first trimester (n-102)	90 (88.2)	12 (11.8)	0.818 (0.407–1.643)	
	At least one dose in the second trimester (n-120)	119 (99.2)	1 (0.8)	0.048 (0.006–0.359)	
	At least one dose in the third trimester (n-24)	24 (100)	0	-	

* Multiple logistic regression analysis. In calculating the odds ratio and 95% confidence interval, the effect of the confounding variables "history of pregnancy outcomes", "underlying disease", and "number of miscarriage history" has been adjusted. ** Including: Elective abortion, spontaneous abortion, and these categories were aggregated with each other in order to use logistic regression

Table 3 The relationship between the type of vaccination, the number of vaccine doses, as well as the time of vaccination and neonatal jaundice in pregnant women referring to comprehensive health service centers (n-610)

Neonatal jaundice Variable		Not occurred	occurred	Odds ratio* (confidence interval 95%)	*P* value
vaccination type	Unvaccinated (n-330)	172 (52.1)	158 (47.9)	1.000	0.048
	Sinopharm (n-225)	92 (40.9)	133 (59.1)	1.680 (1.165–2.422)	
	Other vaccines (n-21)	9 (42.9)	12 (57.1)	1.482 (0.583–3.767)	
	Pre-pregnancy vaccine (n-34)	17 (50.0)	17 (50.0)	1.322 (0.632–2.766)	
number of vaccine doses during pregnancy	Unvaccinated (n-364)	189 (51.9)	175 (48.1)	1.000	0.021
	One dose (n-91)	44 (48.4)	47 (51.6)	1.234 (0.764–1.995)	
	Two dose (n-139)	50 (36.0)	89 (64.0)	1.958 (1.274–3.008)	
	Three dose (n-16)	7 (43.8)	9 (56.3)	1.685 (0.578–4.916)	
timing of vaccination during pregnancy	Unvaccinated (n-364)	189 (51.9)	175 (48.1)	1.000	0.003
	At least one dose in the first trimester (n-102)	51 (50.0)	51 (50.0)	1.083 (0.681–1.724)	
	At least one dose in the second trimester (n-120)	43 (35.8)	77 (64.2)	1.993 (1.266–3.136)	
	At least one dose in the third trimester (n-24)	7 (29.2)	17 (70.8)	3.562 (1.373–9.240)	

* Multiple logistic regression analysis. In calculating the odds ratio and 95% confidence interval, the effect of the confounding variables "history of pregnancy outcomes", "history of neonatal outcomes", and "underlying disease" has been adjusted

timing of vaccination, and the outcomes of maternal mortality and neonatal sepsis.

Discussion

This study aimed to compare maternal and neonatal outcomes (including hypertensive disorders, gestational diabetes mellitus, maternal hospitalization, maternal COVID-19 infection, preterm labor, maternal death, premature rupture of membranes, perinatal mortality, NICU admission, low birth weight and neonatal sepsis) between vaccinated and unvaccinated pregnant women against COVID-19. The results indicated that pregnant women who received the COVID-19 vaccine experienced a reduced risk of miscarriage compared to unvaccinated pregnant women. While other related studies have not reported a similar reduction in miscarriage rates associated with COVID-19 vaccination in pregnant women as observed in our study, the findings suggest that there is no increase in miscarriage rates among vaccinated pregnant women compared to their unvaccinated counterparts [28, 33, 34]. This discrepancy may be attributed to differences in vaccine type, study populations, and other influencing factors. To confirm or refute this finding, further studies with larger sample sizes and more robust designs are necessary to ascertain whether the observed reduction in miscarriage in this study was indeed attributable to vaccination or if other factors were involved. Moreover, this finding implies that vaccination is not only effective as a preventive measure against COVID-19 infection but may also contribute to improving adverse maternal outcomes. Therefore, it holds significance in informing vaccination policies for pregnant women.

In our study, mild neonatal jaundice was observed among pregnant women vaccinated against COVID-19; however, the severity of this jaundice was not significant enough to raise particular concerns or necessitate NICU admission. This contrasts with the findings of Rottenstreich et al. (2021), which indicated a reduction in hyperbilirubinemia in infants of mothers who received the COVID-19 vaccine [35]. The discrepancy in results may be attributed to several factors, including the type of vaccine used in that study (Pfizer with mRNA technology), a larger sample size, and differences in ethnicity and geographic region. Conversely, a study by Minghui Li et al. (2022) reported an increase in neonatal jaundice among infants of mothers vaccinated against COVID-19 compared to unvaccinated mothers [36]. This finding aligns with our results, which may relate to the focus on inactivated vaccines similar to those used in our study. The exact mechanism behind this observation remains unclear and may be influenced by various factors, including differing immune responses of vaccinated mothers and pharmaceutical factors related to the vaccine itself. Additionally, maternal antibodies generated in response to the vaccine, which are transferred to the fetus, may play a role in bilirubin metabolism in the newborn. Given that mild neonatal jaundice typically resolves spontaneously, the clinical significance of this finding warrants further investigation.

Based on the results of our study, hypertensive disorders and gestational diabetes mellitus were not significantly different between the vaccinated group against COVID-19 and those who were not vaccinated. These findings align with a systematic review conducted by Rahmati et al. (2023) and the study by Süt et al., despite their examination of COVID-19 vaccines developed using mRNA technology. It is likely that vaccination, regardless of the platform used, may generally help prevent the exacerbation of these complications [33, 34].

Based on the findings of our study, there was no association between premature rupture of membranes and preterm labor among pregnant women vaccinated against COVID-19 compared to those who were not vaccinated. This aligns with the results of studies by Süt et al. (2024)

and Minghui Li et al. (2022), which also found no increase in premature rupture of membranes or preterm labor among vaccinated women compared to unvaccinated women [34, 36]. In the first study, mRNA platform vaccines were used, while the second study employed inactivated vaccines. However, systematic reviews by Shafiee et al. (2023) and Rahmati et al. (2023) noted a reduction in preterm labor among women vaccinated against COVID-19 compared to unvaccinated group [33, 37]. This discrepancy may be attributed to the larger sample sizes in those studies, which were at least ten times larger than ours, as well as the specific types of vaccines examined. Notably, findings from Hatami et al. (2024) indicated an increase in preterm labor among pregnant mothers vaccinated in the first trimester compared to those who were unvaccinated [38].

Additionally, our study found no increase in maternal hospitalization or maternal COVID-19 infection rates among pregnant women vaccinated with the COVID-19 vaccine compared to those who were not vaccinated. This result contrasts with the findings of Favre et al. (2023), which reported an increased hospitalization rate among unvaccinated pregnant women [39]. However, it is consistent with the results of a review study by Prasad et al. (2022), which indicated that vaccination in pregnant women was not associated with an increase in maternal hospitalization [28]. In a contradictory study, an increase in maternal hospitalization occurred before the outbreak of the Delta variant, while our study and those aligned with our findings focused on the period during the Delta variant outbreak.

The results of our study indicated that vaccination against COVID-19 among pregnant women was not associated with differences in rates of cesarean section or maternal death. Similarly, a systematic review conducted by Rahmati et al. (2023) reported no increase in cesarean sections among vaccinated group compared to unvaccinated pregnant women [33]. The study by Prasad et al. (2022) also found no increase in maternal mortality among pregnant women vaccinated against COVID-19 compared to those who were unvaccinated [28]. This absence of increased risks in the aforementioned outcomes underscores the importance of COVID-19 vaccination, regardless of vaccine type.

Furthermore, our study found that vaccination against COVID-19 did not affect the rates of perinatal mortality or stillbirth. In contrast, the study by Stock et al. (2022) reported that all cases of perinatal mortality occurred exclusively among unvaccinated pregnant women infected with COVID-19 [12]. Additionally, the study by Schwarts et al. (2023) highlighted an increased risk of stillbirth only among pregnant women who were not vaccinated against COVID-19 [40]. The findings of two review studies by Prasad et al. (2022) and Rahimi et al. (2023) indicated a reduction in the risk of stillbirth among pregnant women vaccinated against COVID-19 compared to unvaccinated women [28, 33]. These findings stand in contrast to our results. Notably, in the studies mentioned, mRNA platform vaccines were predominantly used, whereas our study's results were derived from the use of an inactivated vaccine, with 36.9% of cases involving the Sinopharm vaccine.

Neonatal outcomes, including low birth weight, NICU admissions, and neonatal sepsis, were comparable between vaccinated and unvaccinated pregnant women. These findings align with previous studies that reported no significant differences in low birth weight and NICU admissions [28, 33, 34, 41]. Regarding neonatal sepsis, no analogous studies were identified that investigated this outcome among these two groups of women.

A limitation of our study was the inadequate documentation of maternal and neonatal outcomes within the Sib system, resulting in the loss of several samples. Additionally, we encountered difficulties in obtaining information from mothers who did not respond to phone calls. Conversely, a strength of our study was the direct communication with the mothers, which enabled us to collect and accurately record all necessary information.

Future research should investigate the mechanisms underlying the observed changes in specific outcomes, such as mild neonatal jaundice, to enhance our understanding of the effects of COVID-19 vaccination.

Conclusion

The results of this study indicate that the administration of inactivated COVID-19 vaccines does not lead to an increase in adverse maternal or neonatal outcomes. Notably, a reduction in miscarriage rates was observed exclusively within the vaccinated group regarding maternal outcomes, while mild neonatal jaundice without NICU admission was reported among neonatal outcomes. To validate these findings, additional studies with larger sample sizes and comparisons of different vaccine types are warranted. Consequently, it appears that COVID-19 vaccination is generally not associated with a significant increase in risks for mothers or newborns. Consistent with other research, these findings underscore the importance of recommending vaccination for pregnant women as a means to mitigate adverse maternal and neonatal outcomes.

Abbreviations

SARS-COV-2	The virus that causes the disease known as coronavirus disease 2019
ICU	Intensive Care Unit
ECMO	Extra-corporal membrane oxygenation
mRNA	Messenger RNA
LMP	Last menstrual period

Supplementary Information

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Supplementary Material 1

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Author contributions
Z GH: design of the work, have drafted the work, writing the text of the article and samplingM M: design of the work, review and correction of the text of the article, advice on sampling, statistical analysis (corresponding author)P AN: Reviewing and correcting the text of the article, Advice on designing the work, Completing the initial SPSS file for analysis.

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Data availability
The data that support the findings of this study are available from Zahra Gholami but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of Zahra Gholami.However, the data is organized in such a way that each individual is assigned a number, and then the checklist information for that individual is recorded in an SPSS file.

Declarations

Ethics approval and consent to participate
This manuscript was reviewed and approved by "Research Ethics Committees of Rafsanjan University of Medical Sciences". The ethics approval code for this study, IR.RUMS.REC.1402.064, was issued on August 8, 2023. This study was conducted in accordance with the principles of the Declaration of Helsinki.

Consent to publication
Not Applicable.

Competing interests
The authors declare no competing interests.

Informed consent
to participate in this study was obtained from all participants using a predefined form, which was also approved by Ethics Committees of Rafsanjan University of Medical Sciences. The consent form ensured that participants were made aware that their personal information would remain confidential with the researcher. Furthermore, it was communicated that the results would be reported in aggregate form with numbers and figures in the final manuscript.

Clinical trial
Not applicable.

Clinical train number
Not applicable.

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