

COVID19 Vaccination Considerations for Pregnant Women: A Systematic Review

Abstract

Background: Following the coronavirus disease 2019 (COVID-19) pandemic, pregnant women are at a higher risk of developing severe COVID-19 disease. This study investigated whether pregnant women should get vaccinated against COVID-19 or not. Pregnant women in comparison with non-pregnant women. **Materials and Methods:** This study was a systematic review that searched the PubMed, Embase, and Scopus databases using the keywords “COVID-19” OR “SARS-CoV-2” OR “Coronavirus Disease” OR “2019-nCoV” AND “pregnancy” OR “pregnant” AND “vaccine” OR “vaccination” from January 2020 to April 2022. **Results:** Of the 37 selected studies, 15 (40.50%) declared positive views, 9 (24.30%) had inconclusive views, and 13 (35.20%) opposed vaccination due to a lack of adequate information. **Conclusions:** Despite the discrepancies among the studies, one-third of the studies suggested that pregnant women be enrolled in clinical trials to investigate the outcomes of the COVID-19 vaccination on maternal and fetal outcomes. However, the majority of the studies recommended maternal immunization against COVID-19.

Keywords: COVID-19, pregnancy, vaccines, women

Introduction

Since the emergence of the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) in late 2019 and the announcement of the coronavirus disease 2019 (COVID-19) as a universal health crisis by the World Health Organization (WHO), global powers have amassed their capabilities to develop vaccines for this lethal virus.^[1,2] As trials continue, the efficacy and safety of the vaccines developed have been proven; however, relevant data on pregnant women, as a large group of society, are inadequate.^[3] Some studies have shown that pregnant women with severe COVID-19 disease are at a higher risk of miscarriage, stillbirth, or perinatal death than other pregnant women.^[4,5] In addition, disease severity and maternal mortality have been higher in pregnant women than in non-pregnant women.^[5] Therefore, it seems that we are obliged to prevent pregnant women from contracting this lethal virus.^[6] Therefore, when we systematically exclude pregnant and breastfeeding women from most ongoing clinical trials, the results of these studies cannot be directly extrapolated

to pregnant women as the pharmacodynamics and pharmacokinetics of vaccines differ between these two populations.^[7] Therefore, it is necessary to pool available data regarding the pharmacodynamics and pharmacokinetics of COVID-19 vaccines in pregnant women.^[8]

Following vaccines development and distribution among the general public, it seems necessary to conduct a systematic review to evaluate practical advantages and disadvantages of vaccination for pregnant women to continue vaccination. This study investigated whether pregnant women should get vaccinated against COVID-19 or not. Pregnant women in comparison with non-pregnant women.

Materials and Methods

A systematic review study was performed on Scopus, PubMed, and Embase databases using the keywords “COVID-19” OR “SARS-CoV-2” OR “Coronavirus Disease” OR “2019-nCoV” AND “pregnancy” OR “pregnant” AND “vaccine” OR “vaccination.” According to the population, intervention, control, and outcomes (PICO)

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Access this article online

Website: <https://journals.lww.com/ijnmr>

DOI: 10.4103/ijnmr.ijnmr_146_22

Quick Response Code:



How to cite this article: Ghafari Z, Khameneh A, Vahedi L. COVID19 vaccination considerations for pregnant women: A systematic review. Iran J Nurs Midwifery Res 2024;29:389-96.

Submitted: 09-May-2022. **Revised:** 01-Jan-2024.

Accepted: 23-Jan-2024. **Published:** 24-Jul-2024.

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criteria, the population included women who were pregnant, the intervention was the use of the COVID-19 vaccine, the comparison condition was without comparison, and the outcome was vaccine effects from January 2020 to April 2022 in English. The quality of the papers was reviewed using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).

The exclusion criteria consisted of cohort studies, studies on animals, laboratory research studies or research studies related to specific diseases, specific individuals, duplicated articles, and unrelated articles. Letters and case reports were included in this study due to the novelty of the disease and the high-risk nature of the community.

After the selection of articles, their abstracts and titles were surveyed by the two researchers (Z.GH and A.KH) and any disagreement between these researchers was resolved by the third researcher (L.V); the agreement rate (kappa) was 90%. The variables, including the name of the first author, location, sample size, final result, and recommendations, were extracted from the full texts. It should be noted that the authors have conducted several systematic review studies over the previous years.^[9-13]

The data were analyzed with the help of descriptive statistics. The frequency and percentage were calculated in Statistical Package for the Social Sciences (SPSS) software (version 26; IBM Corp., Armonk, NY, USA).

Ethical considerations

In the current study, ethical principles have been considered, and if the study results were utilized, the studies were referenced. This current review was certified by the Ethics Committee of Tabriz University of Medical Sciences, Iran (TBZMED.REC.2021.68435).

Results

Trial flow

The diagram of studies is illustrated in Figure 1. Of the 286 articles retrieved, 96 papers as duplication, 126 articles after reviewing the titles and abstracts, and 27 articles after checking the full texts were excluded.

Study characteristics

Finally, 37 studies (including 2 cohort studies, 18 descriptive studies, 6 review studies, 1 cross-sectional study, 4 letters, 2 case reports, 1 interview, and 1 clinical consensus statement)^[3,4,14-48] were included in the study. Most of them were descriptive articles, and the majority of articles have been published in the USA [Table 1].

Quantitative data synthesis

In the current study, three themes were extracted after evaluation by all authors. The extracted themes were as follows: 1. positive view; experimental opinion, based

on experiences from previous vaccines and suggestion; 2. negative view: the lack of sufficient information about the side effects of vaccines; and 3. inconclusive view.

1. Positive view

Positive views on the use of the COVID-19 vaccine among pregnant women were presented in 15 studies (40.50%). These studies concluded that the vaccination can lead to the immunization of pregnant women and fetuses, and the IgG antibody was detected in the fetuses' blood and the cord blood serum. These studies reported no difference between vaccinated and non-vaccinated fetuses (experimental view as a subtype) in terms of mortality rates and complications.^[15,16,21,23,28,31,37] In one study (2.70%), the authors believed that pregnant women should be included in vaccination programs based on experiences from previous viral vaccines (experimented view as a subtype).^[14] In seven studies (19.00%), the vaccination of pregnant women was suggested as the protection of pregnant women against this lethal virus (suggested view as a subtype).^[17,19,27,35,36,42,47]

2. Negative view

Vaccination was opposed in 13 (35.20%) of the studies due to a lack of adequate information. Based on the results of 12 studies (32.40%), pregnant women should be enrolled in clinical trials regarding COVID-19 vaccination (lack of adequate information in terms of the side effects of vaccines as a subtype).^[3,18,20,29,30,33,34,38,40,43,44,48] A study (2.70%) opposed vaccination due to inadequate data on the effects of maternal immunization (lack of enough information on the effects of vaccination as a subtype).^[45]

3. Inconclusive view

Inconclusive views regarding the side effects and benefits of vaccination were presented in nine (24.30%) studies. Hence, pregnant women should initially receive the necessary explanations about these vaccines before immunization.^[6,22,24-26,32,39,41,46]

Discussion

As vaccination for COVID-19 started following the recent outbreak of the disease, the vaccination of pregnant women, as a high-risk population for the disease, raised debates worldwide. In this study, we evaluated the disadvantages and benefits of maternal immunization against COVID-19.

There is no information on the effects of vaccination on fetuses and neonates during or after pregnancy. Due to the exclusion of pregnant women from clinical trials, none of these studies can specifically clarify the benefits of vaccination in pregnant women. Considering the results of different studies on vaccinated pregnant women, of 37 studies, 15 (40.50%) reported positive outcomes,^[14-17,19,21,23,27,28,31,35-37,42,47] 9 (24.30%) had inconclusive results regarding the side effects and

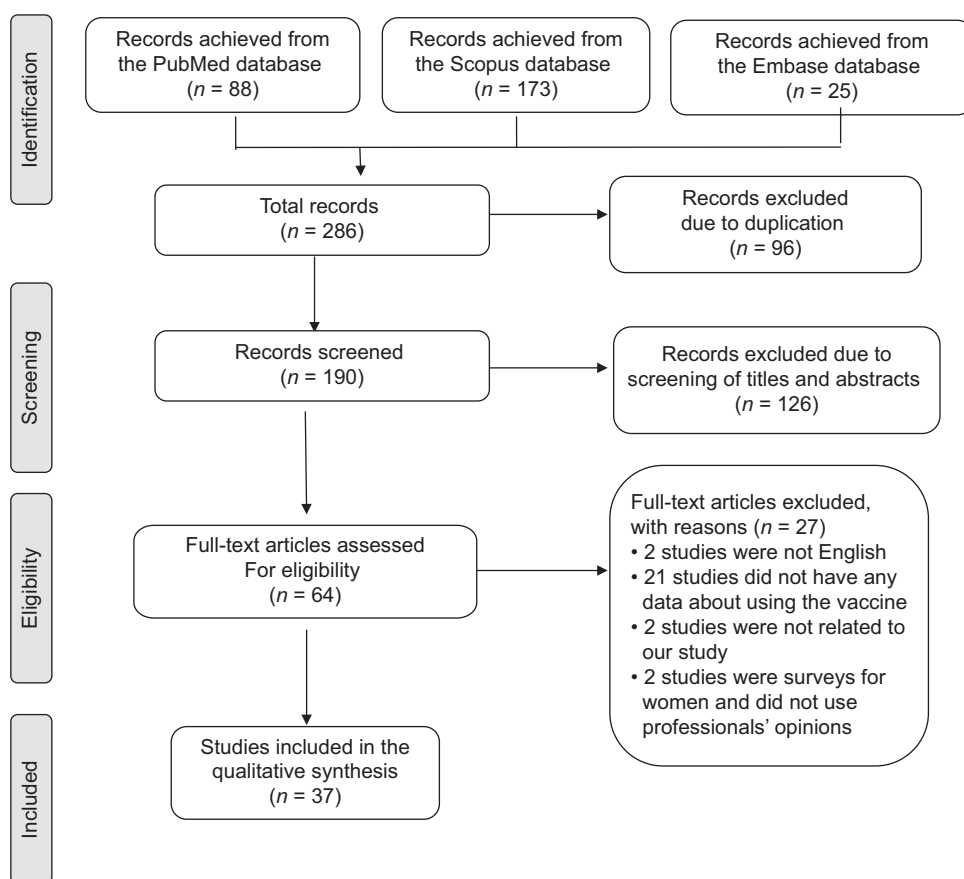


Figure 1: Flow diagram for the inclusion process in this systematic review related to the vaccination of pregnant women against COVID-19

benefits of vaccination,^[6,22,24-26,32,39,41,46] and 13 (35.20%) studies opposed vaccination due to a lack of adequate information.^[3,18,20,29,30,33-34,38,40,43-45,48] Almost all of the studies claimed that pregnant women should be included in clinical trials,^[3,8] and there was an overall positive attitude toward the vaccination of pregnant women; however, vaccination should always be an option and not an obligation for pregnant women.^[16]

Pregnant women are at a higher risk of developing severe COVID-19 in comparison with non-pregnant women, particularly when the infection occurs during the third trimester of pregnancy.^[27] The risk of intensive care unit (ICU) admission has been reported to be about 1% among pregnant women infected with COVID-19, which is greatly increased when they have additional risk factors such as age over 40 years, obesity, chronic hypertension, and diabetes.^[16-20] Pregnant women infected with COVID-19 also present a higher risk for premature birth and fetal growth retardation.^[20]

In a study by Gray *et al.*^[16] on 131 pregnant and breastfeeding women, it was reported that COVID-19 messenger ribonucleic acid (mRNA) vaccines could similarly stimulate the immune system in pregnant women as in non-pregnant women. In the study by Rottenstreich *et al.*^[31] on 20 pregnant women vaccinated with two doses

of mRNA vaccines, antibodies against COVID-19 were detected in both mothers and newborns. Although this study evaluated a small population, its results showed that the immunization led to no serious side effects.^[31] In addition, Gill and Jones^[15] and Paul and Chad^[37] reported the cases of two vaccinated mothers who gave birth safely without any complications.

The novel technology of mRNA vaccines uses non-live viruses, which do not enter the nucleus or change the deoxyribonucleic acid (DNA) in recipients, including pregnant and lactating women.^[21-23]

In addition to positive views on the vaccination of pregnant women, there were debates over the effective transmission of antibodies and passive immunity in neonates.^[21] Due to the lack of sufficient information, Mahase recommended that women not become pregnant for at least 2 months after receiving the COVID-19 vaccine.^[45] Because of the novelty of these vaccines, especially mRNA vaccines, little information is available regarding their potential impacts on pregnancy and fetal outcomes.^[21] Anti-vaccine individuals believe that the vaccine may lead to infertility and abortion in women and intrauterine growth restriction in the fetus.^[21]

Some scientists believe that pregnant women should initially receive the necessary explanations about these vaccines before immunization.^[25,32] In this regard,

Table 1: Characteristics of published studies regarding the vaccination of pregnant women against COVID-19 from January 2020 to April 2022

Authors	Kind of study	Samples	Recommendations	Results
Fell <i>et al.</i> , 2021 ^[14]	Descriptive study	-	Recommends initiating RCTs* with a larger population for using the vaccine in pregnancy	Suggests using the vaccine in pregnant women based on previous studies on other vaccines (positive)
Gill and Jones, 2021 ^[15]	Case report	1	We should inform pregnant women about the risks of getting vaccinated, and this will help them to decide on their own	Positive. Suggests using the vaccine in pregnant women (positive)
Gray <i>et al.</i> , 2021 ^[16]	Cohort study	131	There is no difference in generated robust humoral immunity between pregnant, breastfeeding, and non-pregnant women	Positive. Suggests using the vaccine in pregnant women (positive)
Hayakawa <i>et al.</i> , 2021 ^[17]	Descriptive study	-	There is no need to exclude pregnant women from studies, and after informing them, we should allow them to take part in the studies	It is better to use vaccines in pregnant women as it is fundamental to safeguard, however, many individuals as conceivable by immunization (positive)
Kaur <i>et al.</i> , 2021 ^[18]	A systematic review	-	Pregnant women not vaccinated against coronavirus vaccines	(Negative)
Kounis <i>et al.</i> , 2021 ^[19]	Descriptive study	-	Limiting the use of replicating vaccines in pregnancy might defer or deny pregnant women the main accessible guarantee against lethal sicknesses	Specialists are as yet discussing the circumstances in which vaccines ought to, as a rule, be tried in pregnant ladies (positive)
Saibene <i>et al.</i> , 2021 ^[20]	Clinical consensus statement	33 specialists	All pregnant otolaryngologists and head and neck surgeons working in clinical practice should be given the opportunity to receive the SARS-CoV-2** vaccine quickly, given that the decision is free, individual, and educated, and helped by a well-being expert to separately evaluate the advantages and dangers as per each case	(Negative)
Male, 2021 ^[21]	Descriptive study	3	People in the United Kingdom, the European Union, and the United States have suggested that pregnant people ought to be offered the vaccine where the advantages offset the possible dangers	(Positive)
Minkoff and Ecker, 2021 ^[22]	Descriptive study	-	In the event that the specialist decreases the risk of being contaminated with a perilous infection, similar to the instance of the coronavirus inoculation, and the dangers to the embryo are obscure, then, at that point, shared navigation, as suggested by the FDA***, ought to be attempted, and an illuminated lady's decision ought to be respected	(Abstention)
Ortega Rodríguez <i>et al.</i> , 2021 ^[23]	Letter study	-	Suggestions for the administration of COVID-19 vaccines in pregnancy and breastfeeding	(Positive)
Whitehead and Walker, 2020 ^[24]	Descriptive study	-	Pregnant women should receive the cost of a similar independence proposed to different grown-ups to use in clinical research in clinical trials	(Abstention)
Rasmussen <i>et al.</i> , 2021 ^[25]	Descriptive study	-	Pregnant people and their obstetricians should utilize the restricted accessible information to gauge the advantages and dangers of coronavirus immunization during pregnancy	(Abstention)

Contd...

Table 1: Contd...

Authors	Kind of study	Samples	Recommendations	Results
Stafford <i>et al.</i> , 2021 ^[26]	Descriptive study	-	It was suggested a far-reaching risk-benefit conversation in regard to the absence of security information before coronavirus antibody organization in pregnant ladies, with particular organization for pregnant ladies at most elevated chance of more extreme contamination-related sicknesses until well-being and adequacy of these clever coronavirus immunizations	(Abstention)
Jaffe <i>et al.</i> , 2020 ^[27]	Descriptive study	-	Pregnant individuals should be focused on the general well-being reaction to guarantee fair admittance to protected and compelling antibodies, particularly with arising information proposing coronavirus is more severe in pregnancy	(Positive)
Atyeo <i>et al.</i> , 2021 ^[28]	Case-control	84	-	It is positive; however, this information highlighted an invulnerable protection from producing profoundly provocative antibodies during pregnancy and lactation (positive)
Adhikari and Spong, 2021 ^[6]	Descriptive study	-	Clinicians ought to recognize the possible advantages of immunization weighed against the expected dangers—whether genuine	(Abstention)
Klein <i>et al.</i> , 2021 ^[29]	Descriptive study	-	There is no great explanation to exclude pregnant ladies from stage III preliminaries of coronavirus immunizations, particularly in the event that preclinical security and toxicology information are accessible in creature models	(Negative)
Dashraath <i>et al.</i> , 2020 ^[30]	Correspondence letter	-	Pregnant ladies ought to be remembered for the stage 3 preliminary conventions of adenovirus-vectored immunizations and protein-based antibodies for coronavirus, and the conventions ought to incorporate arrangements for checking maternal and fetal well-being and for documentation of iatrogenic inconveniences, including follow-up of posterity after delivery	(Negative)
Rottenstreich <i>et al.</i> , 2021 ^[31]	Case-control	-	Further examinations will be expected to portray the well-being and adequacy of the different maternal SARS-CoV-2 immunizations accessible and better characterize transplacental immunizer elements at prior gestational ages	It is positive. Our discoveries exhibit that antenatal SARS-CoV-2 immunization initiates a sufficient maternal serologic reaction and can possibly give neonatal assurance through the transplacental exchange (positive).
Van Spall, 2021 ^[3]	Descriptive study	-	Avoidance standards ought to be legitimate in light of information from natural investigations, preliminaries in nonhuman primates, and on account of medications generally utilized for different signs, and observational security information. Clinical trialists and drug translation are too long to be saved. Organizations can supervise maternal-fetal medicine specialists during their induction period. Because pregnancy and lactation are different organic conditions, they should not be joined to the standard of rejection of individual subjects in clinical trials	(Negative)
Rochelle P. Walensky, <i>et al.</i> , 2021 ^[32]	Review study	-	It has been suggested that a pregnant woman should be vaccinated as she would be if she were not pregnant. When the antibody is free for the whole population, a pregnant woman should also be inoculated	(Abstention)

Contd...

Table 1: Contd...

Authors	Kind of study	Samples	Recommendations	Results
Heath <i>et al.</i> , 2020 ^[33]	Descriptive study	-	As the reaction to vaccination in pregnant women is different from that of non-pregnant women, and considering that it is important to evaluate the health of immunization in pregnancy, pregnant women should not be vaccinated	(Negative)
Bianchi <i>et al.</i> , 2021 ^[34]	Descriptive study	-	Pregnant and lactating people ought not to be safeguarded against taking an interest in research, but instead ought to be safeguarded through research	(Negative)
Cohen, 2020 ^[35]	Descriptive study	-	Pregnant ladies ought to be focused on an immunization	(Positive)
Beigi <i>et al.</i> , 2021 ^[36]	Descriptive study	-	Approved coronavirus vaccines should not be kept from pregnant people who are generally qualified to be vaccinated	(Positive)
Paul and Chad, 2021 ^[37]	Case report	-	We encourage different agents to make pregnancy and breastfeeding vaults and to lead adequacy and well-being investigations of the coronavirus immunizations in pregnant and breastfeeding women and their posterity	(Positive)
Lucas and Bamber, 2021 ^[38]	Review study	-	There should be an urged to work to guarantee that current imbalances are tended to as really important as a feature of numerous public and global recuperation programs during and after the pandemic	(Negative)
Rasmussen and Jamieson, 2021 ^[39]	Clinical review	-	Pregnant people considering coronavirus immunization might profit from a conversation with their doctor or other medical care experts in gauging the advantages and possible dangers of inoculation	(Abstention)
Maykin <i>et al.</i> , 2021 ^[40]	Descriptive study	-	Pregnant people justify an equitable distribution of the burdens and advantages of vaccine research	(Negative)
Rubin, 2021 ^[41]	Descriptive study	-	All pregnant people ought to have the option to conclude whether they need to be immunized against a possibly hazardous infection	(Abstention)
Chervenak <i>et al.</i> , 2021 ^[42]	Descriptive study	-	Ethically, patients who are pregnant, breastfeeding, or intending to breastfeed should not be suggested directly about coronavirus inoculation	(Positive)
Costantine <i>et al.</i> , 2020 ^[43]	Review study	-	Pregnant ladies ought to be offered the chance to take part in clinical trials for coronavirus. Instead of naturally barring them, agents ought to talk with specialists in obstetrics, teratology, and obstetric pharmacology. This programmed avoidance is both off-track and not legitimate. Pregnant ladies are completely ready to gauge the moral ramifications of the well-being choices they make for themselves	(Negative)
Costantine <i>et al.</i> , 2020 ^[44]	Letter study	-	The lack of information regarding pregnancy will adversely influence the strength of pregnant ladies and their admittance to interventions in these episodes	(Negative)
Mahase, 2020 ^[45]	Note study	-	The vaccine has not been supported for use in pregnant ladies, and ladies of childbearing age ought to be encouraged to avoid pregnancy for at least 2 months after their second dose. The vaccine ought to likewise not be utilized during breastfeeding	(Negative)
Quintana, 2021 ^[46]	Review study	-	Pregnant women are the last candidates for vaccination after getting enough information about vaccination	(Abstention)
Centor and Riley, 2021 ^[47]	Interview study	-	It is recommended to use the vaccine in pregnant women	(Positive)

Contd...

Table 1: Contd...

Authors	Kind of study	Samples	Recommendations	Results
Kampmann, 2021 ^[48]	Note study	-	The information acquired by researchers and vaccine makers in trials of immunizations can now likewise help naturally avoid little youngsters and pregnant ladies in trials for SARS-CoV-2 vaccines	(Negative)

RTCs*: randomized controlled trials, SARS-CoV-2**: severe acute respiratory syndrome coronavirus-2 FDA***

Quintana^[46] and Rubin^[41] noted that pregnant women should make the final decision after becoming fully aware of the risks and benefits of vaccination, as reiterated by Rasmussen *et al.*^[25] Therefore, pregnant women have the same rights as other people and should be enrolled in clinical trials for COVID-19 vaccines, as argued by Bianchi *et al.*^[34] who opposed excluding pregnant women from clinical trials.^[24,27,35,36] Ceulemans *et al.*^[49] reported that 61% of pregnant and breastfeeding women claimed that they would choose to be vaccinated after being provided information on the risks and benefits of immunization. Overall, the majority of studies recommend maternal immunization with consideration of some items. The limitations of this review include the inclusion of only three scientific databases in the search strategy; the short timeframe of the research interval; the small sample of pregnant women; and the lack of assessment regarding the potential effects of gestational age at the time of vaccination on subsequent outcomes. It should be noted that the Web of Science database was not searched due to accessibility constraints. The main strength of the current study was the use of a systematic review methodology to examine vaccination on pregnant women, a high-risk population, within the context of the COVID-19 pandemic. To build upon these findings, further research through large-scale clinical trials focused specifically on vaccinating pregnant cohorts is warranted.

Conclusion

There were discrepancies among studies on the effects of vaccination on pregnancy outcomes during the COVID-19 pandemic. However, the majority of studies favor the vaccination of pregnant women, especially after informing them of its benefits and risks. It is recommended that pregnant women be enrolled in clinical trials to investigate the maternal and fetal outcomes of the COVID-19 vaccination. Overall, it is required for pregnant women to make an informed decision before receiving these vaccines.

Acknowledgements

The authors would like to thank the Authors of the published studies. This research protocol was approved and supported by Student Research Committee, Tabriz University of Medical Sciences (grant number: 68435).

Financial support and sponsorship

Tabriz University of Medical Sciences, Tabriz, Iran

Conflicts of interest

Nothing to declare.

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