# A Comparative Study on the Safety and Efficacy of COVID-19 Vaccination in Pregnant and Non Pregnant Women

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**Abstract:**

**Introduction:** COVID-19 infection is caused by SARS-CoV-2 virus. Pregnant women being in an immuno-suppressive state are more susceptible to COVID-19 infection leading to many complications like severe illness, ICU admission, need for ventilator support and death. COVID-19 vaccination during pregnancy reduces the risk of severe illness and complications from COVID-19 infection in the mother. COVID-19 vaccination builds anti-bodies that protects the baby also. The main objective of this study was to compare the safety and efficacy of COVID-19 vaccination in pregnant and non-pregnant women.

**Materials and Method:** 50 pregnant and 50 non pregnant women were given 2 complete doses of covaxin/covishield. Adverse events following vaccination and neutralizing antibody titre before and after vaccination was compared between the pregnant and non-pregnant women.

**Results:** The mean age in pregnant women was 24.22 and in non-pregnant women 29.34. P-value< 0.001 which was statistically significant. 43 pregnant and 46 non pregnant women received covaxin. 7 pregnant and 4 non pregnant received covishield. P value 0.523 not statistically significant. After the 1st dose, 12 pregnant women and 15 non pregnant women complained of minor adverse events. P-value 0.652 was non-significant. After the 2nd dose, 10 pregnant women and 14 non pregnant women developed minor adverse events. P-value 0.482 was non-significant. Mean pre vaccination titre in pregnant women was 55.96 and in non-pregnant women 73.53. P-value< 0.001 was statistically significant. Mean post vaccination titre in pregnant women was 78.83 and in non-pregnant women 79.44. P-value 0.799 not significant. Pre and post vaccination titre was compared between the two groups The antibody hike was 22.9% in pregnant women and 6.1% in non-pregnant.. P value was statistically significant.

**Conclusion:** COVID-19 vaccination is completely safe and well tolerated by pregnant women. Vaccination in pregnant women results in immunogenicity and reactogenicity similar to that observed in non-pregnant women.

**Keywords:** COVID 19 vaccination – pregnant women – non pregnant women – adverse events – vaccination titre.

## Introduction

COVID-19 infection is caused by SARS-CoV-2 virus. The severity can range from very mild to severe illness. Pregnant women being in an immunosuppressive state are more susceptible to COVID-19 infection leading to many complications like severe illness, ICU admission, need for ventilator support and death. [1]

Pregnant women with underlying health conditions such as increasing age, obesity, diabetes and hypertension have an increased risk of complications from COVID-19 infection.

There is also an increased risk of preterm labour and still birth. COVID-19 vaccination during pregnancy reduces the risk of severe illness and complications from COVID-19 infection in the mother. COVID-19 vaccination builds antibodies that protects the baby also.[2]

## Materials and Methods

The study was conducted in 100 women (50 pregnant and 50 non-pregnant) attending Govt Rajaji Hospital, Madurai and willing to take COVID-19 vaccination.[3] Study design was Prospective interventional study and the study

period was 6 months from January 22 to june 22. The sample size of 50 cases in each group was taken for convenience for our study.

### Inclusion criteria

- Pregnant women above 18 years with no comorbidities
- Non-pregnant women of reproductive age group

### Exclusion criteria

- History of Anaphylaxis/allergy
- Active COVID-19 infection
- Associated comorbidities like pre eclampsia, gestational diabetes, heart disease, medical disorders complicating pregnancy.
- Thrombosis / thrombocytopenia
- Not willing to take vaccine/ participate in trial

Informed consent was obtained from the women. Pre-vaccination antibody titre was done by ELISA method. They were administered first dose of COVID-19 vaccine.

They were followed up for adverse events like fever, fatigue, myalgia , injection site pain etc.[4] They were asked to come for the second dose of vaccination and were again followed up.

Two weeks after the second dose of vaccination post vaccination titre was done. Titre < 50% was taken as non-significant and > 50% was significant. Primary outcome measure was adverse events following vaccination in pregnant and non-pregnant women. Secondary outcome measure was neutralizing antibody titre after vaccination.

### Statistical Analysis

The data collected from both groups were analyzed and statistically verified by non-parametric chi square. P value of < 0.001 was taken as statistically significant.

### Results

The mean age in pregnant women was 24.22 and in non-pregnant women 29.34. P-value< 0.001 which was statistically significant. 43 pregnant and 46 non pregnant women received covaxin. 7 pregnant and 4 non-pregnant received covishield.[5] P value 0.523 not statistically significant.

After the 1st dose, 12 pregnant women and 15 non-pregnant women complained of minor adverse events. P-value 0.652 was nonsignificant.

After the 2nd dose, 10 pregnant women and 14 non pregnant women developed minor adverse events. P-value 0.482 was non-significant.[figure-1].

### Table 1: Side effects after 1st dose

| Side effects | Pregnant | Non Pregnant |
|---|---|---|
| Yes | 12 | 15 |
| No | 38 | 35 |
| Total | 50 | 50 |
| p value | 0.652 Not significant | |

### Table 2: Side effects after 2nd dose

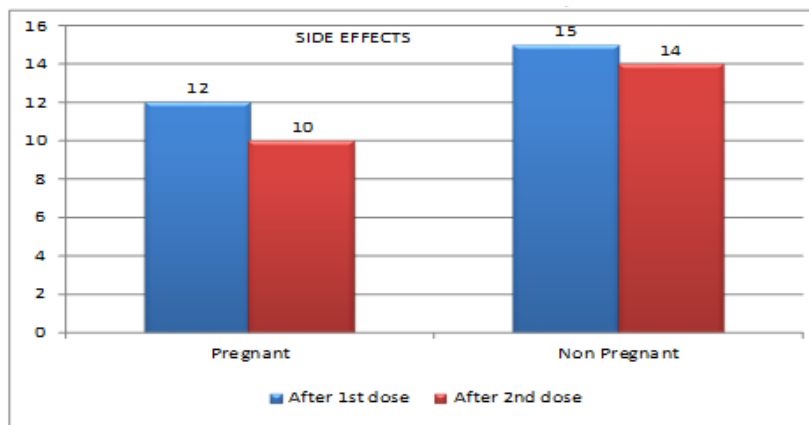| Side effects | Pregnant | Non-Pregnant |
|---|---|---|
| Yes | 10 | 14 |
| No | 40 | 36 |
| Total | 50 | 50 |
| p value | 0.482 Not significant | |



**Figure 1: Side effects after 1st and 2nd dose in Pregnant and non-pregnant**

Mean pre vaccination titre in pregnant women was 55.96 and in non-pregnant women 73.53. P-value< 0.001 was statistically significant. [figure-2]

**Table 3: Pre-Vaccination Titre in % of Pregnant and Non – Pregnant**

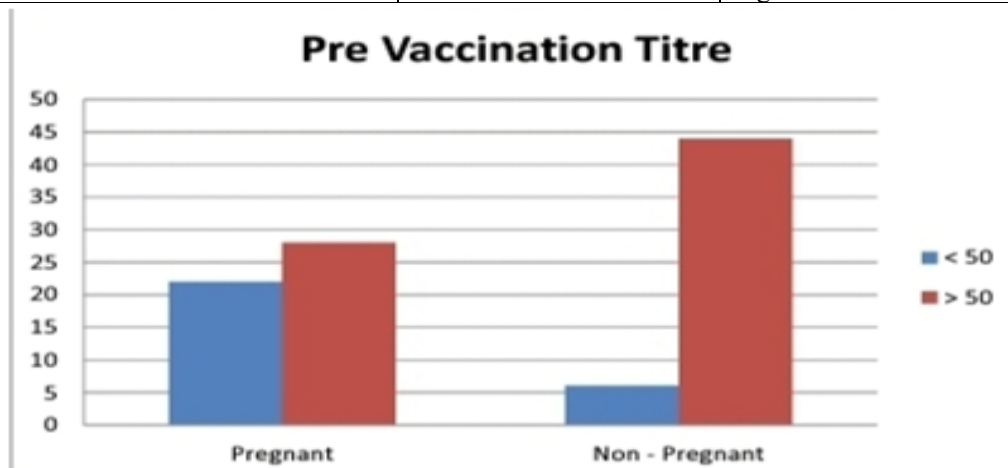| Pre-Vaccination Titre in % | Pregnant | Non - Pregnant |
|---|---|---|
| < 50 | 22 | 6 |
| > 50 | 28 | 44 |
| Total | 50 | 50 |
| Mean | 55.965 | 73.534 |
| SD | 17.869 | 15.106 |
| P-value | <0.001 | Significant |



**Figure 2: Pre vaccination Titre**

Mean post vaccination titre in pregnant women was 78.83 and in non-pregnant women 79.44. P-value 0.799 not significant. [Figure-3]

**Table 4: Post Vaccination Titre in % in Pregnant and Non – Pregnant**

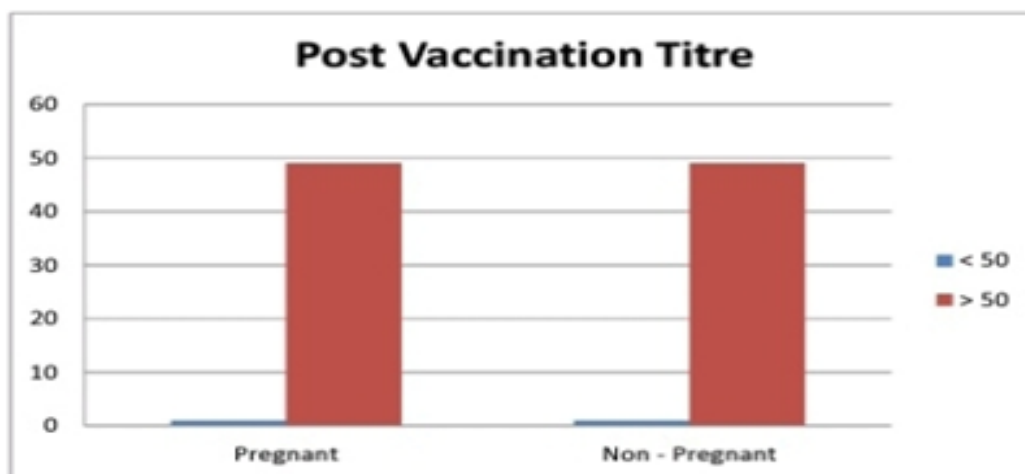| Post Vaccination Titre in % | Pregnant | Non - Pregnant |
|---|---|---|
| < 50 | 1 | 1 |
| > 50 | 49 | 49 |
| Total | 50 | 50 |
| Mean | 78.832 | 79.447 |
| SD | 11.91 | 12.226 |
| P'value | 0.799 Not | significant |



**Figure 3: Post Vaccination Titre**

Pre and post vaccination titre was compared between the two groups The antibody hike was 22.9% in pregnant women and 6.1% in non-pregnant. P value was statistically significant.[figure-4]

**Table 5: Non – Pregnant VS Pre & Post Vaccination Titre %**

|  | Mean | SD | P value |
|---|---|---|---|
| Pre Vaccination Titre in % | 73.534 | 15.106 | 0.034 |
| Post Vaccination Titre in % | 79.447 | 12.226 | Significant |

**Table 6: Pregnant VS Pre & Post Vaccination Titre %**

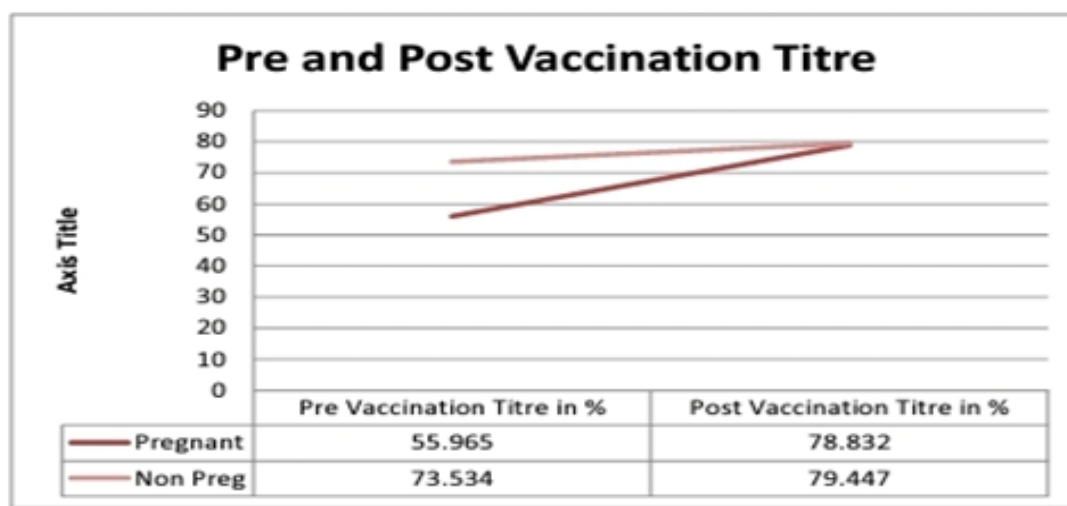|  | Mean | SD | P value |
|---|---|---|---|
| Pre Vaccination Titre in % | 55.965 | 17.869 | <0.001 |
| Post Vaccination Titre in % | 78.832 | 11.91 | Significant |



**Figure 4: Pre and Post Vaccination Titre**

## Discussion

The incidence of adverse events following vaccination was similar between the two groups. They were mild which settled down with rest and analgesics. Pre vaccination titre was low in pregnant women (55.96 vs 73.53) which shows that the innate immune response among pregnant women is low which made them more susceptible to COVID-19 infection.

The antibody hike following vaccination was more in the pregnant women (22.9 vs 6.1) which shows that pregnant women develop strong humoral immunity due to vaccination.

## Conclusion

COVID-19 vaccination is completely safe and well tolerated by pregnant women. COVID-19 vaccination generated robust humoral immunity in pregnant women which protected them from severe illness and complications due to COVID infection. Vaccination in pregnant women results in immunogenicity and reactogenicity similar to that observed in non-pregnant women. The benefits of vaccination outweigh the risk of being infected with COVID. COVID vaccination is the safest and the most effective way for the pregnant women to protect themselves and their babies against severe COVID disease.

## References

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