

An observational study on safety of COVID-19 vaccines in pregnancy – current status and preliminary data based on the Embryotox cohort

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Introduction

Pregnant women with COVID-19 infection are at increased risk for severe disease, stillbirths and prematurity. Since September 2021, vaccination against COVID-19 is recommended for pregnant women after 1st trimester in Germany. The primary aim of this study is to assess pregnancy outcome after exposure to COVID-19 vaccines in pregnancy.

Methods

This surveillance study is based on observational data and includes pregnant women who were vaccinated with any COVID-19 vaccine during pregnancy or at least 30 days prior last menstrual period. Eight weeks after the expected delivery date a standardized follow-up is used to obtain details about pregnancy and neonatal outcomes. To assess potential risks, pregnant women exposed to COVID-19 vaccines will be compared to an unexposed control cohort.

Results

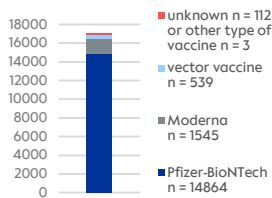


Figure 1: Number of COVID-19 vaccinations

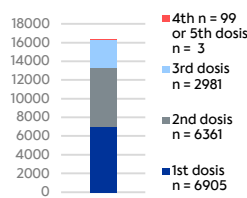


Figure 2: Number of mRNA vaccine doses

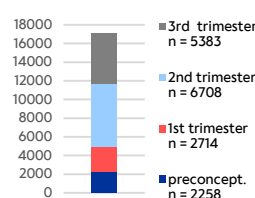


Figure 3: Distribution of vaccinations by trimester

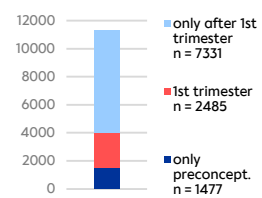


Figure 4: Distribution of pregnancies based on exposure time

In 2021 and 2022 a total of 10,176 prospectively ascertained pregnancies with 17,063 vaccinations (Fig. 1) could be included in the study cohort. In the study cases, more than one COVID-19 vaccination may have occurred in pregnancy. Therefore the number of vaccinations exceeds the number of pregnancies. Figure 2 shows the distribution of the mRNA vaccine doses in the study cohort. More than half of the vaccine doses were administered after 1st trimester (Fig. 3). 2,485 pregnant women have been vaccinated in 1st trimester (Fig. 4).

In the course of the pandemic, the number of women reporting a vaccination changed constantly. Figure 5 shows the cumulative number of study cases in the course of the project. Immediately after approval of the vaccines, only few pregnant women have been exposed. In the further course of 2021, and especially after COVID-19 vaccination was officially recommended for pregnant women numbers increased. In the later course, most women have already been vaccinated before becoming pregnant and fewer vaccinations during pregnancy have been reported. At the beginning of 2023, follow-up of data has been completed for 5,646 pregnancies.

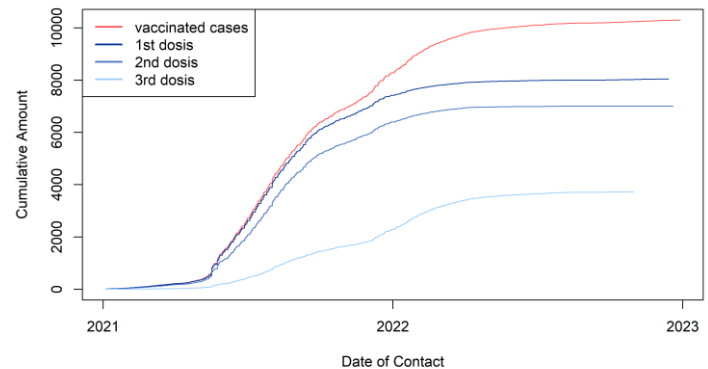


Figure 5: Cumulative number of COVID-19 vaccinated pregnancies over the course of the project

Discussion & Conclusion

It is a challenge to compare different COVID-19 vaccination regimens. There are heterologous vaccinations, basic immunizations as well as boosters in the exposed group. This also applies to vaccines that have rarely been used (vector vaccine and other vaccines). Additionally, the uneven distribution of COVID-19 vaccine exposure over time leads to methodological challenges. Initially, there were predominantly women in the control cohort with inadequate protection against COVID-19. From mid-2022 onward, the control group increasingly included pregnant women who had achieved full vaccination protection prior to pregnancy. Additionally, a final analysis of study data on pregnancy outcome (pregnancy loss, birth defects) will be carried out in 2023.

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