

TERIS Summary

TERIS Agent Number: 6870

Bibliographic Search Date: 12/2022

Agent Name: **COVID-19 INACTIVATED OR ATTENUATED WHOLE-VIRUS VACCINES**

COVID-19 vaccines provide protection against the COVID-19 virus, SARS-CoV-2, and are administered by injection. Several different COVID-19 vaccines have been developed. Inactivated or attenuated whole-virus COVID-19 vaccines consist of whole or fractionated inactivated or weakened SARS-CoV-2 virus.

Magnitude of Teratogenic Risk to Child Born After Exposure During Gestation: UNDETERMINED

Quality and Quantity of Data on Which Risk Estimate is Based: LIMITED

Comments: A SMALL RISK CANNOT BE EXCLUDED, BUT A HIGH RISK OF CONGENITAL ANOMALIES IN THE CHILDREN OF WOMEN IMMUNIZED WITH A COVID-19 INACTIVATED OR ATTENUATED WHOLE-VIRUS VACCINE DURING PREGNANCY IS UNLIKELY.

Summary of Teratology Studies:

MAJOR CONGENITAL ANOMALIES

The frequency of congenital anomalies among infants born to 93 women vaccinated with a COVID-19 inactivated whole virus vaccine anytime during pregnancy was similar to that seen among infants of 160 unvaccinated women in a Chinese prospective cohort study (Li et al., 2023).

ADVERSE PREGNANCY AND NEONATAL OUTCOMES

No difference in birth anthropometrics and Apgar scores were found between 93 women who took a COVID-19 inactivated virus vaccine during pregnancy and 160 unvaccinated women in a prospective cohort study, but the incidence of neonatal jaundice in the vaccinated group was significantly higher (20.4% vs. 7.5%, $p=0.002$) (Li et al., 2023). In a retrospective cohort study of 502 women who were inoculated with a COVID-19 inactivated virus vaccine prior to undergoing frozen-thawed embryo transfer, the rates of livebirths, neonatal and other reproductive outcomes were comparable to those born to 1589 women who were unvaccinated at the time of their frozen-thawed embryo transfer procedure (Cao et al., 2022).

TRANSPLACENTAL PASSAGE OF SARS-CoV-2 ANTIBODIES

Transfer of maternal SARS-CoV-2 IgG antibodies was demonstrated among 95 infants born to mothers who received an inactivated COVID-19 vaccine prior to pregnancy (Yang et al., 2023). The level of SARS-CoV-2 antibodies present in the infants was positively correlated with the number of doses the mother received.

ANIMAL TERATOLOGY STUDIES

Animal teratology studies of COVID-19 inactivated or attenuated whole-virus vaccines conducted by the manufacturer have not been published in the peer-reviewed literature.

Selected References:

(Each paper is classified as a review [R], human case report [C], human epidemiological study [E], human clinical series [S], animal study [A], or other [O].)

Cao M, Wu Y, Lin Y, Xu Z, Liang Z, Huang Q, Li S, Liu H, An C, Luo Y, Liu H, Liu J: Inactivated Covid-19 vaccine did not undermine live birth and neonatal outcomes of women with frozen-thawed embryo transfer. *Hum Reprod* 37(12):2942-2951, 2022. [E]

Li M, Hao J, Jiang T, Deng W, Lu H, Wang S, Wan G, Xie Y, Yi W: Maternal and neonatal safety of COVID-19 vaccination during peri-pregnancy period: a prospective study. *J Med Virol* 95(1):e28378, 2023. [E]

Yang Y, Xing H, Zhao Y: Transplacental transmission of SARS-CoV-2 immunoglobulin G antibody to infants from maternal COVID-19 vaccine immunization before pregnancy. *J Med Virol* 95(1):e28296, 2023. [E]

COVID-19 VACCINE PREGNANCY REGISTRIES

Healthcare providers are encouraged to suggest their patients enroll in the following registries:

V-SAFE

A registry collecting health information from people who received COVID-19 vaccinations in the periconception period or during pregnancy is being maintained by the Centers for Disease Control and Prevention. The registry attempts to assist individuals and healthcare providers to make informed decisions about COVID-19 vaccination.

Pregnant vaccinated people who would like to participate must complete a registration in v-safe (a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html>). People who meet the conditions of the study will be contacted by the registry staff for additional details for enrollment in v-safe.

COVID-19 Vaccine Study

An observational pregnancy study by MotherToBaby has been established for women who received one or more doses of a COVID-19 vaccine during pregnancy or within one month prior to becoming pregnant. All study research will be performed via phone and office visits will not be required.

Additional information about the study can be found at MotherToBaby's COVID-19 Vaccines (<https://mothertobaby.org/ongoing-study/covid19-vaccines/>). Healthcare providers are encouraged to enroll such patients at <https://mothertobaby.org/join-a-study-form/>.

C-VIPER (COVID-19 Vaccines International Pregnancy Exposure Registry)

A registry collecting information from pregnant women who were vaccinated against COVID-19 during pregnancy and is maintained by Pregistry in Los Angeles, Calif. This registry evaluates obstetric, neonatal, and infant outcomes among women vaccinated during pregnancy to prevent COVID-19.

Healthcare providers may find additional information about this study at: <https://www.clinicaltrials.gov/ct2/show/NCT04705116>.

CANADIAN COVID-19 VACCINE REGISTRY FOR PREGNANT AND LACTATING INDIVIDUALS

A registry collecting information from women who are currently pregnant or breastfeeding regardless of vaccination status is maintained by the University of British Columbia in Vancouver, B.C., CANADA and in partnership with other Canadian vaccine surveillance networks. The registry is a longitudinal survey monitoring the safety, effectiveness, and opinions related to the COVID-19 vaccine.

Healthcare providers may find more information about this registry at: <https://covered.med.ubc.ca/>.