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> Safety of COVID-19 vaccines when given in pregnancy

Public Health England

Guidance The safety of COVID-19 vaccines when given in pregnancy

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Background

COVID-19 disease is caused by the SARS-CoV-2 virus (a new coronavirus) that emerged in China in December 2019. Disease symptoms at the time of diagnosis vary from those who have the infection but suffer no ill effects or have minor illness to those requiring breathing and intensive care support. Severe disease is more common with increasing age, particularly from 65 years and over.

COVID-19 vaccine in pregnancy

There is no known risk with giving inactivated virus or bacterial vaccines or toxoids <u>during pregnancy or whilst breast-feeding</u>. However, the COVID-19 vaccines have not yet been tested in pregnancy, so it has been advised that until more information is available, pregnant women should not routinely have these vaccines. As a matter of caution, COVID-19 vaccine is therefore not routinely advised in pregnancy but there are some circumstances in which the potential benefits of vaccination are particularly important for pregnant women. This may include women who are at very high risk of catching the infection or those with certain medical conditions that put them at high risk of suffering serious complications from COVID-19 infection. In such circumstances, a woman may choose to have COVID-19 vaccine in pregnancy following a discussion with her doctor or nurse.

If a COVID-19 vaccine is given to a pregnant woman, she should be reassured that the vaccine does not contain live SARS-CoV-2 virus and therefore cannot cause COVID-19 infection in her or in her baby. Some COVID-19 vaccines contain a different harmless virus to help deliver the vaccine – whilst this virus is live, it cannot reproduce and so will not cause infection in a pregnant woman or her baby.

Evidence so far reviewed by the Medicines and Healthcare products Regulatory Agency (MHRA), the UK regulatory agency responsible for licencing medicines including vaccines, <u>has raised no concerns for safety in</u> <u>pregnancy</u>.

The data for each licensed COVID-19 vaccine in pregnancy is limited because pregnant women are not included in vaccine trials. This is <u>not because of any</u> <u>specific safety concerns but as a matter of caution</u>, like that applied to trials of most other medicines.

If a woman finds out she is pregnant after she has started a course of vaccine, she should complete her pregnancy before finishing the recommended schedule.

COVID-19 disease in pregnancy

Available evidence suggests that COVID-19 infection in pregnancy is unlikely to lead <u>to problems with a baby's development</u> and there have not been any reports of this. There is also no evidence of an increased risk of miscarriage if you become infected during pregnancy.

There is some evidence that babies can be born prematurely to <u>women who</u> <u>are very unwell with coronavirus</u>^[footnote 1]. In a UK study of pregnant women with COVID-19 disease serious enough to require hospital admission (most infected in the second or third trimester), only 6 of 265 babies tested positive for COVID-19 immediately after birth. In line with other studies, this suggests it is uncommon for the natural infection to pass from a woman to her baby. When babies <u>have developed COVID-19 soon after birth</u> they have been well.

The UK Vaccine in Pregnancy surveillance programme

All COVID-19 vaccines given from the first day of last menstrual period to any time in pregnancy should be reported to the <u>UK Vaccine in Pregnancy</u> surveillance programme run by the Immunisation Department of Public Health England.

The objectives of the UK vaccine in pregnancy surveillance are to compile additional information on women who are immunised with specified vaccines whilst pregnant to monitor the safety of such exposures. This data will be used to help better inform pregnant women who are immunised, their families and health professionals who are responsible for their care.

This surveillance is being undertaken in collaboration with the MHRA, the UK teratology information service (UKtis) and with Public Health Scotland, Public Health Wales and Public Health Agency in Northern Ireland.

References

 Knight Marian, Bunch Kathryn, Vousden Nicola, Morris Edward, Simpson Nigel, Gale Chris et al. Characteristics and outcomes of pregnant women admitted to hospital with confirmed SARS-CoV-2 infection in UK: national population based cohort study BMJ 2020; 369 :m2107 <u>←</u>



Coronavirus (COVID-19)

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