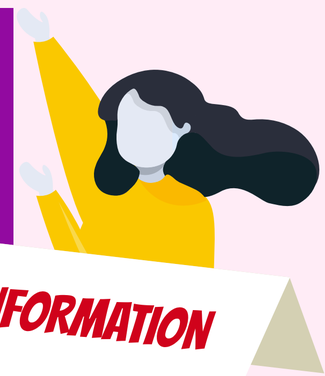
I am pregnant
Should I get a COVID-19 vaccine?



UPDATED INFORMATION

The best way to protect you and your baby from COVID-19 is to get the vaccine

Pregnant women are offered mRNA COVID-19 vaccination between 14 and 36 completed weeks' gestation following an individual benefit/risk discussion with their obstetric care giver.

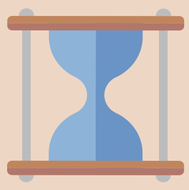
For most people, getting a COVID-19 vaccine as soon as it is available is the safest choice.

This decision aid is intended to help you make an informed choice about getting a COVID-19 vaccine before, during or after pregnancy.

What are my options?

Get the mRNA COVID-19 vaccine

or



Wait until more information is available about the vaccines in pregnancy

Summary

If you are pregnant, mRNA COVID-19 vaccination will be available to you following an individual benefit/risk discussion with your obstetric care giver. Your options include:

1. **Get the mRNA COVID-19 vaccine**
2. **Wait until more information is available about the COVID-19 vaccines in pregnancy**

- Pregnant women with COVID-19 are at increased risk of admission to the intensive care unit (ICU) and death compared with non-pregnant women with COVID-19. Pregnant women with COVID-19 are more likely to experience preterm birth.
- Vaccination is currently the most effective way to reduce the risks associated with COVID-19.
- It is your choice whether or not you get a COVID-19 vaccine during pregnancy.
- The mRNA COVID-19 vaccines do not contain the live COVID-19 virus.
- Results of clinical trials on the COVID-19 vaccine in pregnancy are not available yet and may not be published for many months.
- Current safety data on the use of mRNA COVID-19 vaccines in pregnancy is reassuring and the risks of taking these vaccines when you are pregnant are thought to be small.
- International experts have advised the benefit of getting the COVID-19 vaccine in pregnancy is currently greater than the known risk of the vaccine.
- If you choose to get a COVID-19 vaccine in pregnancy, you should get it between 14 and 36 weeks of pregnancy

What are the risks to a pregnant woman from COVID-19 infection?

- Pregnant women are at similar risk of becoming infected with COVID-19 compared with non-pregnant women of the same age. Most pregnant women who are infected with COVID-19 will only experience mild to moderate symptoms.
- COVID-19 is more serious for pregnant women. Pregnant women with symptoms of COVID-19 infection are more likely to need admission to an ICU or to die when compared with women without COVID-19 or similar aged non-pregnant women.
- During the most recent wave of COVID-19 infections in Ireland (Nov 2020 to April 2021), women who were pregnant had a higher risk of ICU admission than women in the same age group who were not pregnant.
- COVID-19 in pregnancy may increase the risk of stillbirth, preterm birth and the need for the infant to be admitted to a neonatal unit.

Irish Medicines in Pregnancy Service
ROTUNDA HOSPITAL DUBLIN
National Women & Infants Health Programme
National Immunisation Advisory Committee (NIAC)
INSTITUTE OF OBSTETRICIANS & GYNAECOLOGISTS

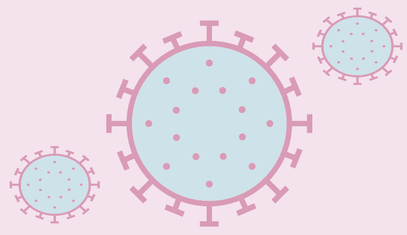
I am pregnant
Should I get the COVID-19 vaccine?

Option 1: Get the mRNA COVID-19 vaccine

About this option: This option includes getting a vaccine following an individual benefit/risk discussion with your obstetric care giver.

What are the positives of this option?

1. Vaccination is currently the most effective way to reduce the risks associated with COVID-19. Getting the vaccine may:
- Reduce your risk of getting infected with COVID-19.
- Reduce your risk of getting severely unwell from COVID-19.
- Reduce your risk of pregnancy complications, such as preterm birth and stillbirth.
- Reduce the risk of you transmitting COVID-19 to others around you.



2. Vaccination may protect your baby from COVID-19:
- Emerging data indicate that maternal COVID-19 antibodies can cross the placenta.

3. COVID-19 vaccination is recommended after 14 weeks of pregnancy:
- After 14 weeks, the risk of miscarriage is reduced compared with early pregnancy and most of the body systems are fully formed.

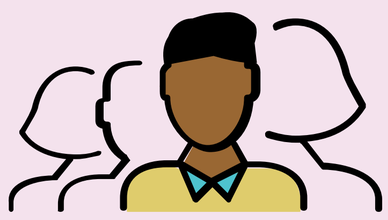
4. Other vaccines are routinely recommended in pregnancy with good information on safety:
- For example, flu and pertussis (whooping cough) vaccines. These vaccines cannot cause infection in you or your unborn infant and do not contain ingredients which are known to be harmful.

5. Current safety data on the use of mRNA COVID-19 vaccines in pregnancy is reassuring:
- Available studies in animals do not indicate harmful effects or any safety concerns about the COVID-19 vaccines in pregnancy.
- Over 106,000 pregnant women have had a mRNA vaccine in the US*. Nearly 5,000 women have volunteered for detailed follow-up. No safety concerns have been identified among these women or their babies. Long term follow-up is ongoing.
- International experts have advised the benefit of getting the COVID-19 vaccine in pregnancy is currently greater than the known risk of the vaccine.

*reported to the Centres for Disease Control (CDC) in the United States as of 03/05/21

What are the negatives of this option?

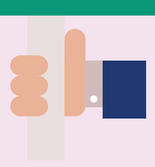
1. The amount of information on pregnancy outcomes following COVID-19 vaccination is currently limited:
- We do not know for sure if there are negative impacts of giving COVID-19 vaccines in pregnancy.
- Trials of the COVID-19 vaccines are now taking place in pregnant women. The results are not available yet.
- However, many mRNA vaccines have been given to pregnant women and current safety data is reassuring.



2. You may get some side-effects from getting the vaccine:
- Common side effects are reported in more than 1 in 10 people and include fatigue, headache, sore arm, fever and muscle or joint pains. These usually resolve within 2 days.

If you choose this option....

The first dose should be at or after 14 weeks and the second dose ideally by 36 completed weeks of pregnancy



- **Less than 14 weeks:** Wait until after 14 weeks before getting your first dose of the COVID-19 vaccine. If you received the first dose before becoming pregnant the second dose can be given after 14 weeks.
- **Between 14 and 36 weeks**: Get the first dose at or after 14 weeks and the second dose ideally by 36 weeks. If the second dose is not given by 36 completed weeks, speak with your doctor about when to get your second dose - you may have to delay it until after you have had your baby.
- **More than 36 weeks:** Speak to your doctor if you have not received your first dose of the vaccine. Your doctor may still recommend you to get the vaccine when you are pregnant.

If you get the COVID-19 vaccine, you should continue to follow current public health advice, including advice on social distancing, wearing a mask and hand hygiene.

Are there any other things to think about if I choose this option?

- If you develop a fever (>38°) after your vaccination, paracetamol can be used safely during pregnancy. If you cannot take paracetamol speak to your doctor or midwife about other options.
- You should still get your flu and whooping cough (pertussis) vaccine when recommended. You should leave a gap of 14 days between your COVID-19 vaccine and another vaccine.
- If you do get the COVID-19 vaccine and later discover you are pregnant there is no need to be overly concerned. Some women included in the initial vaccine trials became pregnant. The rate of miscarriage in these women was not different to the rate of miscarriage in the general population.
- If you have already had COVID-19 you should still consider getting the mRNA COVID-19 vaccine. Although previous COVID-19 infection does provide some protection, vaccination is still recommended. If you have had laboratory-confirmed COVID-19 in the previous 6 months you will only need one dose of vaccine.
- If you have already received your first dose of Vaxzevria® (COVID-19 Vaccine AstraZeneca) you should speak to your doctor about when to get your second dose of Vaxzevria®.

If you do receive the COVID-19 vaccine when pregnant, please inform your maternity unit so it can be recorded in your maternity record.

Option 2: Wait until more information is available about the vaccines in pregnancy

About this option: Trials of the COVID-19 vaccines are now taking place in pregnant women. You may choose to wait until the results of these trials are published before getting your COVID-19 vaccine, or to wait until after you have had your baby.

What are the positives of this option:

1. Not getting a vaccine means you will not have any side effects from COVID-19 vaccination

What are the negatives of this option:

1. Not getting a vaccine means you will still be at risk of getting COVID-19

- COVID-19 is dangerous. It is more serious for pregnant women.
- Pregnant women who develop symptoms of COVID-19 infection are more likely to develop serious disease, need admission to ICU or to die when compared with women without COVID-19 or similar aged non-pregnant women.
- If you get infected with COVID-19 you may be at increased risk of stillbirth, preterm birth and your infant may be more likely to be admitted to a neonatal unit.

2. You won't be able to enjoy the benefits afforded to fully vaccinated people when meeting with others

3. The results of the pregnancy trials may not be published for many months

- You may have to wait until after you have your baby to get your vaccine.

Who should consider this option?

It might make sense for you to wait for more information, or wait until after you have had your baby if:

- You think getting a vaccine will make you very nervous.
- You are more worried about getting the vaccine compared with the known risks of getting COVID-19
- You have had a severe allergic reaction or anaphylaxis with injected medicines.
- You are not at higher risk of getting COVID-19 and can maintain strict compliance with public health advice and measures to reduce the risk of COVID-19.

Are there any other things to think about if I choose this option?

You should only choose this option if:

- You can always wear a mask according to public health advice.
- You and the people you live with can socially distance from others for your whole pregnancy.
- Working from home is an option for you.
- Your community does not have a high or increasing rate of COVID-19.

What do the experts recommend?

The HSE and the National Immunisation Advisory Committee (NIAC), a group of independent experts in Ireland, recommend that pregnant women should be offered mRNA COVID-19 vaccination between 14 and 36 weeks' gestation following an individual benefit/risk discussion with their obstetric care giver. mRNA vaccination is now recommended, or is available, for all pregnant women in other countries, including France, the UK, Austria, Israel, the US and Canada.

The European Network of Teratology Information Specialists (ENTIS), a European group of experts in the use of medicines in pregnancy, have stated that current safety data are reassuring, leading to a favourable benefit/risk ratio for COVID-19 vaccination in pregnancy and that vaccination is currently the most effective measure to reduce the risks associated with COVID-19 in pregnant women.

What do the other women say?

"I decided to get the Covid 19 vaccine as I considered the information and wanted to protect myself and my baby. I had no ill effects, in fact, my arm wasn't even sore"

What about COVID-19 vaccines when breastfeeding?

Breastfeeding offers substantial health benefits to women and their breastfed children. Emerging evidence also suggests that antibodies to COVID-19 are secreted in breastmilk of vaccinated mothers, potentially offering protection to breastfed babies.

COVID-19 vaccines have not been studied in breastfeeding and it is unknown if any COVID-19 vaccine components are excreted in human milk. There are no theoretical risks from getting these vaccines when breastfeeding. If COVID-19 mRNA vaccine remnants pass into breastmilk, they would be digested in the baby's stomach.

The World Health Organisation does not recommend discontinuing breastfeeding after vaccination. The HSE recommends that breastfeeding mothers should be vaccinated according to their risk grouping. If you were vaccinated while pregnant, antibodies against COVID-19 may pass into your breastmilk and give your baby some protection.

What is an mRNA vaccine?

Currently available mRNA vaccines include Comirnaty®- Pfizer/BioNTech and COVID-19 Vaccine- Moderna. mRNA vaccines do not contain the live COVID-19 virus. These vaccines include the genetic instructions for your body to make viral proteins that will prompt an immune response. The body then produces antibodies against the virus. These antibodies block the virus from entering cells and can prevent disease. The risk of getting mRNA vaccines in pregnancy is thought to be very low due to the rapid breakdown of mRNA in the body. To date, over 106,000 mRNA vaccinations in pregnancy have been reported to the Centres for Disease Control (CDC) in the United States*. Current safety data on the use of mRNA COVID-19 vaccines in pregnancy is reassuring.

*as of 03/05/21

Where can I find out more information?

A Q&A document produced by the Institute of Obstetricians and Gynaecologists and NIAC is available on the RCPI website. This includes additional information for those planning a pregnancy or undergoing fertility treatment. If you require further information or support, please speak with a health care professional.

About this decision aid

This decision aid is for people who are pregnant and who are eligible to receive the COVID-19 vaccine in line with the national COVID-19 vaccination programme. This decision aid is intended to help you make an informed choice about whether or not to get the COVID-19 vaccine before, during or after pregnancy. This decision aid was produced by the Irish Medicines in Pregnancy Service (IMPS) at the Rotunda Hospital and The Institute of Obstetrics and Gynaecology (IOG), and was endorsed by the National Immunisation Advisory Committee (NIAC) and the National Women and Infants Health Programme (NWIHP). This decision aid has been modified from the decision aid produced by the Massachusetts Shared Decision Making: COVID Vaccination in Pregnancy working group at the University of Massachusetts Medical School – Baystate. This decision aid (Version 3.0) was updated on 04/05/21.The decision aid will be updated to include additional COVID-19 vaccines when they are available in Ireland.

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