Public Health England

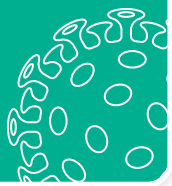
Understanding COVID-19 infection in pregnant women and their babies

Public Health England (PHE) is working with St George's, University of London (SGUL) to understandthe risk of infection in babies born to mothers who develop coronavirus infection in pregnancy.

You can find out more about the coronavirus outbreak on this website:

www.gov.uk/government/topical-events/coronavirus-covid-19-uk-government-response

We would like to invite you to take part in the periCOVID study because you are pregnant and have recently been diagnosed with coronavirus infection. Before you decide to take part, we would like you to understand why we are doing this, and what it would involve for you. Please ask us if there is anything that is not clear.



Why are we following-up pregnant women with coronavirus infection?

The novel coronavirus outbreak is spreading rapidly and we know very little about the risk of infection in pregnant women and if or how the infection might be transmitted to babies or how it may affect them. them. In order to understand this we would like to take regular samples from pregnant women and their babies to test for the novel coronavirus and immunity against the novel coronavirus. The donated samples will be treated as a gift to PHE and SGUL meaning that we will not be able to return them to the participants.

Do I have to take part?

It is up to you to decide whether or not to take part and you should not be placed under any pressure to do so. If you do decide to take part in the periCOVID study you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part you are still free to withdraw from the study at any time and without giving a reason.

What do you want me to do?

If you decide to take part, you will be asked to sign a consent form. If you are unable to sign then we will ask your next of kin to sign on your behalf. The doctor or midwife looking after you or the research team at your hospital or at SGUL (if enrolled directly into the study) will complete an online questionnaire about your health and, after your baby is born, the health of your baby. This questionnaire will use an identification number and will not have your name or any other personal information about you.

What samples will you take?

We will arrange all the tests for you with the doctors and midwives who are looking after you or the research team. For women who are enrolled directly into the surveillance by SGUL, we will provide you with all of the equipment required for the collection of samples and to safely return them to the laboratory.

It is at your doctor or midwife's discretion whether the samples are taken, however they will remain your property until they are sent to SGUL.

What samples will you take at delivery?

When your baby is born, the following samples will be collected from you: vaginal swab, amniotic fluid swab, placental swab, cord blood, and breast milk (colostrum) if possible.

We also plan to collect the following samples from your baby after birth. A blood sample will be collected from your baby if cord blood was not collected, nasal, urine and stool.

What samples will you take after delivery?

After your baby is born, we would like to collect a throat swab, urine and rectal swab sample from you and a nasal swab, urine and stool sample from your baby around the same day every week (between Monday and Wednesday to allow the samples to be received at SGUL before the weekend) for 6 weeks.

The doctor or midwife looking after you or the research team will help collect these samples while you and your baby are in hospital. When you are discharged home, we will either give you the kits before discharge or post the kits to you and you will be able to take the samples yourself and post them back to us. Your local doctor or midwife or research team will remind you to take the weekly samples by phone, email and/or text.

In addition to these swab samples, we would also like to collect a breastmilk sample from you, and one blood sample from you and your baby at around 6 weeks after delivery. Your local doctor or midwife, or research team will arrange this with you at a time and place that is convenient to you and your baby.

What will happen to our samples and data?

Your samples will be coded with an identification number that is unique to you and your baby. The identification number will be stored with all the other samples until they are tested. We will test your samples for coronavirus infection, to see if your immune system has made antibodies against the virus. Finally, we will sequence the genome of the virus to better understand its biology.

The samples will all be destroyed after testing. However, should you wish, you have the opportunity to anonymously donate your and your baby's samples to SGUL for future studies and/or to anonymously donate your blood samples to Public Health England Seroepidemiology Unit collection. If you do not want to donate your samples, this decision will not prevent you from taking part in the periCOVID study.

Your personal data will be stored in accordance with the General Data Protection Regulations (GDPR) and the Data Protection Act 2018.

We may retrieve your anonymised data from our partners working on the UKOSS and PANCOVID studies. This information will not have your name or any identifiable information attached to it so it will not be directly traceable to you and your baby. Should you wish, you also have the opportunity to allow your and your baby's anonymised data and/or results to be used for future studies. If you do not want us to retrieve your data from UKOSS or PANCOVID, or to store yours or your baby's data or samples use in them to be used for future studies, these decisions will not prevent you from taking part in the periCOVID study.

What are the benefits to me?

We will tell you your and your baby's results when all the testing is complete, which will likely be towards the end of the surveillance. Taking part will also help provide important information to protect pregnant women, their babies and healthcare staff looking after them. We will also produce a report of the overall results for the pregnant women in the surveillance for Public Health England and publish them in a medical journal.

What are the disadvantages?

For some, blood sampling may cause momentary discomfort at the site of the blood draw, possible bruising, redness, and swelling around the site, bleeding at the site, feeling of light-headedness when the blood is drawn, and rarely, an infection at the site of the blood draw. Whenever possible, we will aim to take some extra blood when you and your baby have your routine blood tests. We do not anticipate any other disadvantages from taking part.

What if I change my mind?

If you no longer want to be involved, you can withdraw from the surveillance at any time by contacting us at pericovid@phe.gov.uk. The samples you have already provided will continue to be processed but you and your baby will not be asked to provide any more samples.

What should I do now?

If you would like to volunteer, all you have to do is to complete and sign the consent form. If you have any questions concerning the taking of blood, or the collection of the other samples, please do not hesitate to ask the team.

If you have any further questions regarding this surveillance, please feel free to contact us at periCOVID@phe.gov.uk.

Who has reviewed the protocol for this surveillance?

This research has been reviewed by PHE Research and Development team and the PHE Research Ethics and Governance Group (PHE REGG NR0188-PeriCOVID).

What should I do if I have any concerns?

If you have any concerns, please talk to us. If you are still unhappy, you can contact:

Complaints Manager
Strategy Directorate
Wellington House
133-155 Waterloo Road
London
SE1 8UG

Email: complaints@phe.gov.uk

Public Health England

periCOVID

St George's University of London

COVID-19 infection in pregnancy and the newborn (code: periCOVID)
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