Mama

Infant Immune Response Information Leaflet

Please read this leaflet to find out more, and scan the QR code to watch the video.

If you would like further information, please speak to a member of the clinical team.

FUNDED BY
NIHR | National Institute for Health and Care Research

We are inviting all infants born to mothers enrolled in the MAMA study to be considered for follow up investigations of their immune system with 3 blood tests over a year. This will provide valuable information about the impact of being exposed to biologic (monoclonal antibody) medications during pregnancy on the development of babies' immune systems.

Please take time to read the information carefully so you understand what participation would involve. If you have any questions, please contact the study team. Thank you for taking the time to consider volunteering for investigations.

Summary

- This follow up programme is an optional part of the MAMA Study and will look at a subset of babies born to mothers participating in the MAMA Study.
- Your baby can participate in this part of the MAMA study whichever group you (mother) are allocated to.
- The tests will look at the impact of biologics taken during pregnancy on the immune system of your baby.
- We aim to enrol 176 babies.
- Babies will have three study visits, at ages 2, 5 and 13 months.
- Our study team will visit you and your baby at home.
- During each of the three visits the babies will have blood samples taken (each of a volume equivalent to about two teaspoons) and samples of nasal fluid collected. We will use a local anaesthetic cream to numb the skin for blood tests.
- All babies of women participating in the MAMA study will be followed up with questionnaires about health and development even if you do not agree for the extra tests.

What is this follow up programme about?

The follow up programme will provide information about the immune system of babies born following exposure to biologic medications during pregnancy.

There are concerns about possible effects of biologics on babies' immune systems, and some baby vaccinations are routinely delayed. Until recently, most women were advised that they should stop their biologic drugs during pregnancy and avoid these drugs in the second and third trimester; however, due to growing evidence of their safety for mums and babies during pregnancy, recent national guidance (British Society for Rheumatology, 2023) has stated that biologics may be continued throughout pregnancy if required to control active/severe disease.

The babies will have blood tests taken to check their response to the infant vaccines as well as looking at their immune system blood cells. Samples of nasal fluid will also be collected to look at the immune response in the lining of the airways. The results will be reviewed to see if there is any difference in the development of the immune system in babies whose mothers continued their biologic medication into the third trimester compared to those whose mothers stopped their biologics before 28 weeks of pregnancy.

This will provide important information for the future when helping women decide to continue taking biologics during pregnancy and if any special considerations should be given to the newborn babies.

Can my baby take part?

The MAMA Coordinating Team, is made up of two research groups based at the University of Oxford who are working together on the MAMA study, the National Perinatal Epidemiology Unit (NPEU CTU) and the Oxford Vaccines Group (OVG).

A trained member of staff from the Oxford Vaccine Group will visit you and your baby at home to collect the samples. There is a possibility that some babies may live too far away for this to be practical, a staff member from MAMA Coordinating Team will inform you if this is the case.

What will happen?

A member of the MAMA Coordinating Team will contact you by telephone or email. You will have the opportunity to ask questions and decide if you would like your baby to take part.

The first study visit needs to take place before your baby has their first vaccinations (around 2 months of age). At the first visit a parent will be asked to sign a consent form. Your child will have a blood sample taken. We use an anaesthetic cream to help numb the skin and a second person may distract your child if needed. Taking blood from children can sometimes be difficult and it is important to us that your child is not too upset by the process. If necessary, we may ask to make a second attempt. We will take a maximum of 4 ml of blood (less than a teaspoon) at this visit. Blood sampling can cause bruising or pain, minimised with local anaesthetic cream.

A sample of nasal fluid will be taken by placing a small soft synthetic material about 2cm long into your baby's nostril and leaving it pressed against the inside for about a minute. This is not uncomfortable although some babies may not like it. As with the blood test, the second person will help to distract your baby.

The second visit will take place around a month after your baby has completed their primary immunisations (around 5 months of age). The study team will provide you with anaesthetic cream and instructions for how to put it on. A maximum of 4ml of blood (less than a teaspoon) and nasal fluid samples will be collected.

The third visit will take place around a month after the 1-year immunisations. A maximum of 6ml of blood (just over a teaspoon) and nasal fluid samples will be collected.

During all visits we will review your baby's red book for their vaccination history and ask some questions about their medical history.

Table to show what will happen in the study

	Visit 1	Visit 2	Visit 3
Age	2 months	5 months	13 months
What happens at the visit?			

Written consent  Blood test  Nasal Fluid sample 

Does my baby have to take part?

No, taking part in research is voluntary. If you decide you would like your baby to take part in this part of the MAMA study and later you change your mind, you can withdraw them from the study at any time. You don't have to give a reason. If you withdraw your baby from the study, no further data will be collected and we will keep the samples, unless you request that they are destroyed.

There will still be the opportunity to provide health outcomes for your child to the MAMA study (number of admissions to hospital, development etc) regardless of whether they have blood tests taken as part of the study.

What are the benefits of taking part?

Your child's immune system will be looked at in more detail to check that they have responded appropriately to vaccinations and if additional vaccine doses or boosters are recommended, the study team will discuss with you and your GP.

What will happen to the samples obtained in the study?

Samples will be labelled with an ID number, not your baby's name. Samples will be processed at Oxford University Hospitals laboratories and processed and stored at Oxford Vaccine Group laboratory and sent to other laboratories in the UK and Europe for analysis.

You will also be asked for permission to store samples (including cells and DNA) in the Oxford Vaccine Centre Biobank. This is a collection of samples, like a library, and allows the samples to be stored once this study is finished. You can choose to say no to the biobank but continue with this part of the study.

What will happen if the results from blood tests are abnormal?

We will contact your GP if we detect abnormalities in your child's blood tests which need further investigation. We will not contact you or your GP if the results are not significantly abnormal.

What will happen to the information collected in the study?

Your child will be given a study number, which will be used on study paperwork and all samples. Any paper notes will be held securely at the MAMA Coordinating Centre. With your permission, we may need to obtain information from your child's medical records to confirm medical history or vaccinations received.

The people who analyse the information collected and the samples will not be able to identify your child and will not be able to find out your child's name or your contact details. If you withdraw from the study, we will keep the information about your child that we have already obtained, including blood samples, but if you prefer you can request for the samples to be destroyed (they may already have been analysed).

In summary, what would happen if I would like my child to take part in this component of the MAMA study?

- When you sign the study consent form, indicate that you are interested in your baby taking part.
- Once your baby is born, we will contact you by phone or email to see if you are still interested in taking part and answer any questions you may have.
- We would make an appointment to see you and your baby at your home to sign the consent form and collect the samples.

Thank you for taking the time to read this information sheet and for considering taking part in this study.

Contact address:

The MAMA Coordinating Team

NPEU Clinical Trials Unit
National Perinatal Epidemiology Unit (NPEU)
Nuffield Department of Population Health
University of Oxford, Old Road Campus, Oxford OX3 7LF

T: 01865 743859 **E:** ***mama@npeu.ox.ac.uk***
W: ***www.npeu.ox.ac.uk/mama***

FUNDED BY NIHR | National Institute for Health and Care Research