Mama

The Monoclonal Antibody Medications in inflammatory Arthritis: stopping or continuing in pregnancy (MAMA) study

Participant Information Leaflet

Information for pregnant women with inflammatory arthritis who are being treated with a biologic.

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.

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The MAMA Study: Key Information

This information leaflet provides information about the MAMA Study

- You have been given this information leaflet because you are pregnant, and have inflammatory arthritis which is being treated with one of the biologics we are studying.
- The MAMA study is designed to find out whether it is better for women who are pregnant with inflammatory arthritis to continue taking their biologic medication throughout pregnancy or to stop by 28 weeks gestation.
- Across the United Kingdom (UK), we aim to involve 328 women in the MAMA study.
- Out of those 328, women will be randomly allocated by a computer system to either continue taking their biologic throughout pregnancy, or to stop by 28 weeks gestation.
- Other than stopping or continuing your current biologic no other changes will be made to your arthritis treatment as a result of being in the study.
- During your pregnancy we will ask you to complete a simple questionnaire when you join the study and then every month to report your arthritis symptoms via an app on your phone (or on paper if you prefer).
- At 3, 6, and 12 months after the end of your pregnancy, we will ask you to complete a questionnaire about you and your baby's health.
- At 24 months we will be asking some participants to complete a questionnaire which will include some standard questions about your child's development that are often used to routinely follow-up children at this age.
- Data about you and your baby will also be collected from your health records.

We'd like to invite you to take part in our research study.

This research is for pregnant women with inflammatory arthritis who are being treated with a biologic.

What is the MAMA Study?

The MAMA study is designed to find out whether it is better for women who are pregnant with inflammatory arthritis to stop or to continue taking biologic medications. There is good evidence that these medications are safe for the developing baby. Recent national guidance (British Society for Rheumatology, 2023) has stated that biologics may be continued throughout pregnancy if required to control active/severe disease. Therefore, most people who are taking biologic medications for arthritis will continue to take them in the first half of pregnancy.

We know that these medications may affect the way a baby's immune system responds to live vaccinations. Some women will choose to stop biologics in the last 3 months of their pregnancy, in order that their baby can have a full routine vaccination schedule. Some women, however, will continue to take biologics throughout their entire pregnancy, and their baby will have one or two of their vaccinations (known as the "live" vaccinations) delayed for 6 months.

Managing arthritis well in pregnancy is important because severe arthritis can lead to worse outcomes in pregnancy and biologics can help manage pain and inflammation levels. Stopping biologic medications may mean that arthritis is at risk of flaring, which would require treatment with steroids or other medications which can impact on the pregnancy.

It is not a straightforward decision when it comes to stopping or continuing biologic medications in the second half of pregnancy. We don't know the impact of stopping or continuing biologics on how well a person's arthritis is controlled in pregnancy or in the postnatal period (after the baby is born). The MAMA study is looking to answer this question.

Why have I been invited?

You are being invited to take part in this research study because you are pregnant, and have inflammatory arthritis which is being treated with one of the biologics we are studying. Across the United Kingdom (UK) we aim to involve 328 women in the MAMA study.

Do I have to take part?

No. It's entirely up to you to decide whether or not you take part. If you decide you do not wish to take part, you do not have to give a reason and your care will not be affected in any way. If you do take part and you then change your mind about this later, you are free to withdraw from any aspect of the study at any time. Your care will not be affected and will follow the standard approach in this hospital. We will only collect and use data relating to events occurring up to the time of withdrawal.

What will happen if I decide to take part in the MAMA Study?

If you agree to take part you will be asked to sign a consent form. By signing this form you agree to take part in this research study. You will be randomly allocated by a computer system to either continuing to take your biologic throughout your pregnancy, or to stop by 28 weeks of pregnancy. This will be decided by chance so you will have an equal chance of being in either group.

The continuing group
Women in this group will continue taking their biologic throughout pregnancy.

OR

The stopping group
Women in this group will stop their biologics before the third trimester (28 weeks) of pregnancy, and restart no earlier than 2 weeks post-pregnancy.

Other than stopping or continuing your current biologic by 28 weeks gestation no other changes will be made to your arthritis treatment as a result of being in the study.

During your pregnancy we will ask you to complete a simple questionnaire when you join the study. We will then ask you to complete short questionnaires every month until the end of your pregnancy, and at 3, 6, and 12 months after the end of your pregnancy. These questionnaires will ask you about your arthritis symptoms and treatment and can be completed via an app on your phone (or on paper if you prefer). The questionnaire takes only 1-2 minutes to complete. You can also tell us about details of some other events such as arthritis flares at any time.

At 3, 6, and 12 months after the end of your pregnancy we will also ask you to complete questionnaires to find out about you and your child's health and quality of life. These questionnaires will take 5-10 minutes to complete. Data about you and your baby will also be collected from your health records.

At 24 months we will be asking some participants to complete a longer questionnaire which will include some standard questions about your child's development that are often used to routinely follow-up children at this age. Whether you are asked to complete this questionnaire will depend on when you join the study. The person you speak to about consent will be able to tell you what to expect.

Can my baby take part?

There will be an option for your baby to be considered for another part of the study looking at your baby's immune system. This part of the study would involve 3 visits to your home to take small blood samples (approximately

1-2 teaspoons of blood for each sample) when your baby is 2 months, 5 months, and 13 months of age.

You do not have to decide whether you would be happy for your baby to have these blood tests yet. But we will ask you to let us know if you are happy to be contacted by the MAMA Coordinating Centre about this after your baby is born. You do not have to agree to your baby having blood tests in order to take part in the MAMA study.

What should I consider?

For women who continue their biologics throughout pregnancy, your baby may have one or two of their vaccinations delayed. This will be discussed with your clinical care team. For this reason, if you are planning on moving to a country with high rates of tuberculosis within 6 months of giving birth or if any of your close relatives or people you are living with have current, active tuberculosis, you cannot take part in MAMA.

Are there any possible disadvantages or risks from taking part?

Both continuing and stopping using biologics beyond 28 weeks of pregnancy are routine practice in the UK. Stopping your biologic medications can increase the risk of disease activity and flares during pregnancy. If your arthritis gets worse, or you experience a flare, you may decide to restart your biologic after discussion with your clinical team. Rarely, some women report that their biologic does not work as well as before, but for most women, restarting their biologic or an alternative biologic is effective for controlling their disease. Continuing your biologic medication in pregnancy may have possible effects on babies' immune systems, and some baby vaccinations may be delayed. This will be discussed with you as part of your clinical care, if you have any concerns please discuss them with your rheumatologist or clinical team.

What are the possible benefits of taking part?

Whilst there are no direct benefits to taking part, your contribution may help answer an important question, which could be of benefit to women and their babies in the future.

Will I be reimbursed for taking part?

There is no payment for taking part in the study. But when we send you the questionnaire when your baby is 2 years old we will send you a £15 high street voucher as a thank you for taking part.

You and your data

What will happen to the results of this study?

At the end of the study (after all participants have finished the trial and the data is cleaned and locked), the results will be analysed and published in a medical journal. We will write our reports in a way that no one can work out who took part in the study. We will also share the results at conferences, on our website, and with inflammatory arthritis support groups. We will send you a copy of the results at the end of the trial. Unidentifiable data from this study may also be shared with other groups who are carrying out similar work in the future.

What personal information will you collect about me and my baby?

If you decide to take part, we will be using information from you, you and your baby's health records, and other central NHS registries (or equivalent national databases) in order to undertake this study and will use the minimum personally-identifiable information possible. We will collect some personal information about you and your baby, including name, NHS number (or equivalent), date of birth, address, and contact details (e.g. email address and telephone number).

This information will be sent to the MAMA Coordinating Centre, which 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).

The team will use your name, home address, and contact details, to contact you about the research study.

Keeping your data safe

We will store any research documents with personal information about you and your baby, such as consent forms, and any other identifiable information securely at the University of Oxford for 25 years after the end of the study, planned to be in 2030, as part of the research record. A copy of the consent form from this study will be kept in your medical records for as long as those records are retained.

Responsible members of the University of Oxford, the King's College London, the Medicines and Healthcare products Regulatory Agency (MHRA), the MAMA Coordinating Centre, or the host Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Where else may my data be shared?

Your personal identifiable information (your name and email address) may be viewed by individuals from Oxford Research Software Engineering Group (OxRSE), University of Oxford to allow you to interact with the study via an app on your smartphone. Your GP and rheumatologist will also be told you are taking part in this study.

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study. It is the data controller, and is responsible for looking after your information and using it properly.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at: ***compliance.web.ox.ac.uk/individual-rights***

Please see our web link for further information about how we protect your data:

www.npeu.ox.ac.uk/ctu/privacy-notice

Participation in future research:

We would like to conduct some further research in the future to assess your child's longer-term health, neurodevelopmental, and educational outcomes in relation to taking biologics during pregnancy. To do this, we need your consent to use you and your child's NHS number (or equivalent), and other identifiers in order to access your child's routine health and education data via national databases.

Any further research would be subject to ethical review, and we would ensure it is compatible with the purpose of this study. This is an optional part of this study, you do not have to consent to this in order to take part in MAMA. You also have the right to opt-out of these databases. If you do not wish the

NHS to use your health records for the purposes of supporting any health related research in the future, please visit: ***www.nhs.uk/your-nhs-data-matters/manage-your-choice*** to make your choice.

We will also ask permission to potentially contact you again in the future to find out how your child is getting on as they grow up, if you agree your personal details, such as name, phone number and email address, will be stored in Oxford and shared with the research teams in King's College London.

What if there is a problem?

In the first instance, you can talk to the clinical team looking after you who will help you with your concern. You can also contact the local research team, either the research nurses or the Principal Investigator; their contact details are on the back page of this leaflet.

Please note that information reported on the study app and questionnaires is not sent directly to your GP, obstetrician, midwife or rheumatologist. If you need medical advice for you or your baby, please contact your clinical team directly.

If you wish to complain about any aspect of the way that you or your baby has been treated you may use the normal National Health Service complaints procedures and the Patient Advice and Liaison Service (PALS) at your hospital will advise you about this.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Professor Marian Knight (details on page 12) or you may contact the University of Oxford Research Governance, Ethics & Assurance Team (RGEA) on 01865 616480, or the head of RGEA, email ***RGEA.Complaints@admin.ox.ac.uk***.

Further Information

Who is organising and funding the study?

The study is funded by the National Institute for Health and Care Research (NIHR153577) which is the research arm of the NHS. The study is sponsored by the University of Oxford and is being run by the National Perinatal Epidemiology Unit Clinical Trials Unit at the University of Oxford in collaboration with the King's College London. Professor Marian Knight and Dr Kate Duhig are the lead Investigators.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given a favourable opinion by London - Central Research Ethics Committee.

Thank you for reading this information.

If you have any queries or concerns or would like help with any aspect of the trial please contact:

Local contacts

Principal Investigator
{_PI_}

{_PRIMARY HEADING_}
{_PRIMARY_}

Contact address:

The MAMA Study Team

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We use the term 'women' throughout our website and our publications to refer to those who are planning to become pregnant, are pregnant, and give birth. We acknowledge that not all people who are pregnant and give birth identify as women, and it is important that evidence-based care for maternity, perinatal and postnatal health is inclusive.

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