Mama

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

MAMA Information Leaflet

Information for women who may be planning pregnancy and are currently being treated on a biologic for inflammatory arthritis

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, or planning a pregnancy, 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.

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 given this information?

You have been given this information because you may be planning a pregnancy and are currently being treated on a biologic for your inflammatory arthritis. If you do become pregnant there may be an opportunity for you to take part 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.

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. 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.

There will be an option for your baby to be considered for another part of the study looking at your baby's immune system.

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:

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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