Giant PANDA

Pregnancy ANtihypertensive Drugs: which Agent is best?

Participant Information Leaflet

We would like to invite you to take part in the Giant PANDA study, run by the University of Birmingham (study sponsor) and King's College London

Study summary

- This study is looking at which blood pressure medication is best for pregnant women and people who are pregnant with high blood pressure and their babies.
- We will compare two medications called labetalol and nifedipine. Both have been widely used to treat high blood pressure in pregnancy for many years. Both are considered safe in pregnancy.
- Around half of participants taking part in this study will be asked to take labetalol and the other half nifedipine. The group you are in will be decided by chance. Your healthcare team would be happy with you having either.
- All participants will continue to receive their usual NHS care during pregnancy.

What does taking part involve?

Contact 1 - At start of study
We will ask you some questions about your health. We will let you, and your healthcare team, know if you are in the labetalol or nifedipine group.

Contact 2 - Two weeks later
We will ask you some questions about your health and how you are finding the blood pressure medication (up to 30 minutes).

After that each month we will ask you to complete a short online survey until your baby is born. We will look at the healthcare records for you and your baby (or babies). We will not need direct contact with you for this.

1. Why are we doing this study?

Around 10% of pregnant women and people in the UK have high blood pressure in pregnancy. If high blood pressure is not managed well, it can lead to serious problems for the woman and baby. The Giant PANDA study is looking at the two most commonly used medications (labetalol and nifedipine) to treat high blood pressure in pregnancy. Doctors in the NHS usually choose one or the other as their preferred treatment. We want to find out which is best for pregnant women and their baby (or babies).

2. Why am I being asked to take part?

You are being asked to take part in this study because you and your doctor have decided that you need medication to treat your high blood pressure during pregnancy (up to 36 weeks').

3. Do I have to take part? What if I change my mind?

No. Taking part is entirely up to you and will not affect your current or future NHS treatment. If you decide to take part but change your mind later, you are free to stop at any time. Any information you have given up to that point will be used in the study results.

4. What will happen if I take part?

You will be asked to complete a consent form to say that you agree to take part in this study.

After agreeing to take part, you will be asked to complete a short survey (less than 5 minutes) about how you are feeling. We will also fill out some information about your medical and pregnancy history.

Half the women in this study will be chosen to take labetalol. The other half will be chosen to take nifedipine. The group you are in will be chosen at random (by chance) by a computer.

To make sure you are treated safely, you and your healthcare team will know what group (labetalol or nifedipine) you have been asked to take.

We will check in with you two weeks later and ask you to complete four short surveys (taking less than 30 minutes) about how you are finding your medication. We can do this:

- over the phone
- by sending a link to your phone to complete online (we use a company linked to the study database provider to send this text to you and your data is held in line with GDPR)
- in person if you need to visit the hospital,

whichever is easier for you.

If you agree, we will look at the healthcare records for you and your baby (or babies) during the pregnancy and shortly after birth.

5. How do I get my medication, and do I need to stay on this medication for my entire pregnancy?

Once you know which group you are in (labetalol or nifedipine), your doctor will prescribe the medication in the normal way. You can collect your medication from the pharmacy as usual.

The maternity team will continue to measure your blood pressure and check your medication throughout your pregnancy, as usual. If needed, they can change the dose of your medication, add in extra medication or switch to a different medication. You can continue to take part in this study, as this is all important information for us.

6. What are the advantages and disadvantages of taking part?

Taking part will help us to understand how best to treat women with high blood pressure in pregnancy. Because you were about to be prescribed one of these two medications to treat your high blood pressure, there is very little risk to taking part. The only disadvantage is the additional time spent with the study

team. We will keep these contacts as brief as possible. If it is easier for you the two-week check in can be over the phone or by email.

The doctor or healthcare professional prescribing your medication will explain any side-effects as they usually would. You can ask them for more information at any time if you are not sure. The commonest side-effect reported for both medicines in pregnancy is headache. Some women also report dizziness or breathlessness. All participants will continue to receive their usual NHS care during pregnancy while in this study.

7. Who will know about me taking part in this study? How will we use information about you?

We will place a note in your pregnancy folder so that everyone looking after you knows that you are taking part in this study and which medication you are on.

We will need to use information from your medical records (you and your baby's/babies') for this study. This is to help us find out what happens to you and your baby (or babies) up to when you are discharged after birth. This information will include your initials, NHS number, name and contact details. People will use this information to do the research or to make sure that the research is being done properly. We will keep all information about you safe and secure for up to 25 years. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. We may share anonymised data (where you can't be identified) with other researchers for research purposes. Personal information recorded will be regarded as strictly confidential and will be handled and stored in accordance with GDPR 2018. You can find out more about how we use your information by emailing the study's sponsor Data Protection Officer *dataprotection@contacts.bham.ac.uk* and at *www.hra.nhs.uk/information-about-patients/*

8. Can I still take part if I am already taking both medications or if I am unable to take either labetalol or nifedipine?

You can contribute to this study by completing the surveys and allowing us to look at the healthcare records for you and your baby (or babies) if you are:

- already taking both medications
- cannot take one or the other
- if you do not want your medication group to be chosen at random.

Although we need the randomisation to be sure which medication is best, your information is still very useful to us.

9. More information about this study *[study website url]*

Who funded this study?

This study is funded by the National Institute for Health and Research (NIHR).

Who runs this study?

The Chief Investigator for this study is Professor Lucy Chappell at King's College London. She is running this study with the Birmingham Clinical Trials Unit, University of Birmingham.

Who reviewed, gave permission to do this study?

This study is sponsored by the University of Birmingham. It has been reviewed and approved by the London South East Research Ethics Committee.

What if I have a problem or concern?

If you have any concerns about any aspect of this study, please ask a member of the Giant PANDA research team or contact the study manager on *Giant-PANDA@trials.bham.ac.uk*

What if I have a complaint?

If you wish to formally complain about any aspects of this study, you can do this through the Patient Advice and Liaison Service (PALS) *[local PALS details].* They can provide support for any complaints or queries you may have regarding the care you receive as an NHS patient.

NHS indemnity covers all clinical treatment provided. In the unlikely event that you are harmed as a direct consequence of taking part in this study the University of Birmingham have insurance in place.

Study manager contact details

For any additional study information please contact the study manager on *Giant-PANDA@trials.bham.ac.uk*

Next steps

I want to take part – Read on for the consent form.

I am not sure yet if I want to take part - You do not have to decide if you want to take part in the study now. Take time to think about it. Women can take part in this study up to the 36th week of pregnancy. Your research team will let you know the best way to contact them if you wish to take part at a later date.

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Informed Consent Form

Study number:	*[NNNN]*

Please initial*

1.	I confirm that I have read the Participant Information Leaflet above. I have had the opportunity to consider the information and ask questions.	☐
2.	I understand that my participation is voluntary and that I am free to stop the study at any point without giving any reason, without my medical care or legal rights being affected. Any information up to that point can be used in the study results.	☐
3.	I understand that relevant sections of the healthcare records for me and my baby (or babies) may be looked at by members of the research team where it is relevant to my taking part in this study. I give permission for these individuals to have access to my records.	☐
4.	I understand that the details provided below in this consent form will be shared with the research team to contact me when needed.	☐
5.	I understand that the information collected about me may be used to support other research in the future and may be shared anonymously with other researchers.	☐
6.	I agree to take part in the above study.	☐

Trial only

7.	I agree to be randomised to one of the medication groups (labetalol or nifedipine)	☐

Optional

8.	Please tick this box if you wish to be contacted about future research studies using the contact details provided. If you agree to be contacted it does not mean you have to take part.	☐
9.	I agree for the study records from me and my baby (or babies) to be linked with long term health data collected routinely (with no further participation needed by me).	☐

Contact details

Email address	
Contact number	

Study results

Please tick this box if you wish to be sent a summary of the results by email at the end of the study.	☐

Participant

Participant name _____

Signature _____

Date _____

Name of person taking consent

Researcher name _____

Signature _____

Date _____

**For paper consent*

UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

KING'S College LONDON