**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 with high blood pressure and their babies.

We will compare two medications called labetalol and nifedipine. Both have been widely used in the NHS to treat high blood pressure in pregnancy for many years and are both considered safe in pregnancy.

Around half the women 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 and your healthcare team would be happy with you having either.

* All women 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 and for your agreement to take part in this study. 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 check in with you, ask you some questions and ask you to complete some short questionnaires about how you are finding the blood pressure medication (up to 30 minutes).

After that we will ask you if you can complete some short online questions once a month until birth. We will look at the healthcare records for you and your baby (or babies) but we will not need direct contact with you for this.

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1. **Why are we doing this study?**

Around 10% of pregnant women in the UK have high blood pressure in pregnancy. If high blood pressure is not managed well, it can lead to serious complications for the woman and baby. The Giant PANDA study wants to look 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 at treating blood pressure in pregnant women without having troublesome side-effects for the woman or baby.

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1. **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, and you are pregnant (up to 34 weeks’).

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

No, taking part is entirely voluntary 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 still be used in the study results.

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1. **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. In addition, women at some hospitals will be asked to complete some additional short online surveys.

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

Half the women in this study will be chosen to take labetalol and the other half to 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 questionnaires (taking less than 30 minutes) about how you are finding your medication. We can either do this over the phone, by sending a link to your phone to complete online, or in person if you need to visit the hospital - whichever is easier for you. We use a company linked to the study database provider to send the text to you with your data held in line with GDPR.

With your agreement, we will look at the healthcare records for you and your baby (or babies), to look at your health during the pregnancy and shortly after birth.

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1. **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 and you can collect your medication from the pharmacy just 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. But you can continue to take part in this study, as this is all important information for us.

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1. **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 medication to treat your high blood pressure, there is very little risk to taking part. The only possible disadvantage is the additional time spent with the study team. We will keep these contacts as brief as possible, and 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, and you can ask them at any time if you are not sure. The commonest side-effect reported for both drugs in pregnancy is headache. Some women also reported dizziness or breathlessness. All women will continue to receive their usual NHS care during pregnancy while in this study.

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1. **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 you and medical records (for mum and baby) for this research project. This is to help us find out what happens for 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 check your records 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/*](http://www.hra.nhs.uk/information-about-patients/)

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

If you are already taking both medications, or cannot take one or the other, or if you do not want your medication group to be chosen at random, you can contribute to this research by doing all the data collection. Although we need the randomisation to be sure which medication is best, your information is still very useful to us.

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1. **More information about this study** [***wrh.ox.ac.uk/research/osprea***](https://www.wrh.ox.ac.uk/research/osprea)

**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 and 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) *PALS@ouh.nhs.uk*that 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 34th 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.