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Blood pressure response assessment by pregnancy antihypertensive drug treatment

Submission date
20/04/2022

Recruitment status
No longer recruiting

Registration date
09/05/2022

Overall study status
Ongoing

Last Edited
17/01/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Around one in ten women will have high blood pressure in pregnancy. Controlling high blood pressure in pregnancy with medicines is important to protect the health of the woman and her baby. There haven't been enough studies to know which is the best blood pressure medicine to use in pregnancy. Previous studies have shown that the medicines commonly used do not work well in all women.
A large study (GIANT PANDA study) of the two main blood pressure medicines, called labetalol and nifedipine, aims to find out which one works best to treat high blood pressure, and to check if there are any effects on the baby. The researchers also want to see if there are differences in how well how these two medicines control blood pressure over a short time frame (12-24 hours), and to see if this helps us understand how these medicines work throughout pregnancy. They will also look at whether a woman's ethnic background and kidney markers in her blood are related to how well blood pressure is controlled by these medicines. This may help us better understand why some blood pressure medicines do not work well in some pregnant women.

Who can participate?
Pregnant women aged 18 years and over with high blood pressure in pregnancy, who are participating in the GIANT PANDA study.

What does the study involve?
Participants are provided with a monitor that automatically measures their blood pressure and heart rate every 30-60 minutes. They will be asked to wear the blood pressure monitor for 12-24 hours on up to three occasions during their pregnancy, coinciding with scheduled antenatal appointments where possible. Each time women complete this monitoring they will be asked to provide a urine and blood sample. Women will also be provided with a diary to record the times they take their blood pressure medicine, any side effects from the medicine, and the times they wake up and go to sleep during these monitoring periods.

What are the possible benefits and risks of participating?
Taking part will help the researchers to understand how best to treat women with high blood pressure in pregnancy. The possible disadvantages are the additional time spent with the study team and the inconvenience of having a blood test taken or wearing the blood pressure monitor

for 24 hours. All women will continue to receive their usual NHS care during pregnancy while in this study.

Where is the study run from?
The Birmingham Clinical Trials Unit is running the study with the University of Manchester (UK)

When is the study starting and how long is it expected to run for?
March 2022 to March 2024

Who is funding the study?
National Institute for Health Research (NIHR) Efficacy and Mechanisms Evaluation (EME) Programme (UK)

Who is the main contact?
Natalie Barry
Natalie.barry@mft.nhs.uk

Study website
https://www.birmingham.ac.uk/research/bctu/trials/womens/giantpanda/index.aspx

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
307769

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V1.0, IRAS 307769, CPMS 51935

Study information

Scientific Title
Blood pressure response Assessment BY Pregnancy ANtihypertensive Drug treAtment: the BABY PANDA study

Acronym
BABY PANDA

Study objectives
Study rationale: to determine the short-term blood pressure (BP) response of antihypertensive agents, focusing on nifedipine and labetalol, using 24-hour ambulatory BP monitoring, and to explore the association between short-term BP response and longer-term clinical effectiveness. 24-hour ambulatory BP profiles may provide mechanistic insight into the clinical effectiveness of nifedipine versus labetalol in pregnancy, as well as having the potential for translation into clinical practice as a tool for early identification of women with a suboptimal response to the prescribed antihypertensive agent. The collection of blood and urine samples in this study will allow the assessment of drug adherence (as assessed by drug metabolite assays), and markers of renin-angiotensin system activation may provide mechanistic insight into differing responses to nifedipine and labetalol in pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/02/2022, Wales Research Ethics Committee 6, Swansea (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road, East Cardiff, CF11 9AB, UK; +44 (0)7920 565664, +44 (0)2920 230457; Wales.REC6@wales.nhs.uk), ref: 22/WA/0047

Study design
Prospective observational cohort study, aligned with the GIANT PANDA study (ISRCTN12792616)

Primary study design

Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
https://www.birmingham.ac.uk/research/bctu/trials/womens/giantpanda/index.aspx

Health condition(s) or problem(s) studied
Hypertension in pregnancy

Interventions
24-hour ambulatory blood pressure monitoring, occuring up to three times in the pregnancy. Urine and blood samples will be collected up to four times in pregnancy. Urinary drug metabolite analysis will be performed. Renin and aldosterone concentrations will be measured in maternal blood.

Intervention Type
Mixed

Primary outcome measure
The principal outcome is 8-hour systolic BP post-dose response to labetalol/nifedipine. This is defined as the proportion of systolic BP readings ≥140 mmHg/number of BP readings within that time period. The post-dose 8-hour response window will begin at the time of the ingestion of the antihypertensive agent, within the 24-hour ambulatory BP monitoring episode (as captured by the participant's self-reported diaries). The time of the first dose will be classified as timepoint 0.

Secondary outcome measures
Blood pressure:
1. 8-hour diastolic BP post-dose response to labetalol/nifedipine (defined as the proportion of diastolic BP readings ≥90 mmHg/number of BP readings, where the 8-hour post-dose window is defined as per the primary outcome)
2. 8-hour BP post-dose response to labetalol/nifedipine (defined as the proportion of BP readings ≥140 mmHg systolic or ≥90 mmHg diastolic/number of BP readings, where the 8-hour post-dose window is defined as per the primary outcome)
3. 8-hour BP post-dose variability expressed as reading to reading variability and standard deviation
4. 8-hour post-dose mean arterial pressure (MAP)
5. 8-hour post-dose mean maternal heart rate (HR)
6. 8-hour BP response (systolic, diastolic, proportion of readings ≥140 mmHg systolic or ≥90 mmHg diastolic/number of BP readings, and BP variability described for women on combination therapy (labetalol and nifedipine or another antihypertensive agent).
7. 24-hour post-dose systolic BP response to antihypertensive agent: the proportion of systolic BP readings ≥140 mmHg/number of BP readings

8. 24-hour post-dose diastolic, combined and BP response to antihypertensive agent: the proportion of diastolic BP readings ≥90 mmHg/number of BP readings.
9. 24-hour post-dose BP response to antihypertensive agent: the proportion of BP readings ≥140 mmHg systolic or ≥90 mmHg diastolic/number of BP readings.
10. 24-hour post-dose BP variability
11. 24-hour post-dose mean arterial pressure (MAP)
12. 24-hour post-dose mean maternal heart rate (HR)

Blood and urine samples:
1. Adherence to medication measured using urinary drug metabolite concentrations at various timepoints across gestation
2. Renin and aldosterone concentrations measured using blood and urine samples at various timepoints across gestation

Overall study start date
01/03/2022

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. Women will be approached for recruitment to the BABY PANDA study after they have agreed to participate in the GIANT PANDA study (either randomised within the intervention study or participating in the observational arm)
2. Pregnancy ≤34+6 weeks' gestation
3. Diagnosis of pregnancy hypertension (chronic or gestational hypertension)
4. Aged 18 years or over
5. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
320

Key exclusion criteria
Diagnosis of preeclampsia

Date of first enrolment

16/05/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
St Mary's Hospital
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
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SE1 7EH

Sponsor information

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Sponsor type

University/education

Website
http://www.birmingham.ac.uk/index.aspx

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/05/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from Prof. Jenny Myers (jenny.myers@manchester.ac.uk) on reasonable request. Requests for the final dataset can be made through the chief investigator in accordance with the data-sharing policies of the University of Manchester, King's College London, and Birmingham Clinical Trials Unit, with input from the co-investigator group where applicable.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 1.2	15/11/2022	25/04/2024	No	No