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Blood pressure in the postnatal period

Submission date
04/02/2019

Recruitment status
No longer recruiting

Registration date
06/02/2019

Overall study status
Completed

Last Edited
06/05/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
High blood pressure in pregnancy is an increasingly common complication that increases the risk of adverse pregnancy outcomes including maternal and infant death, damage to the mother's liver and kidneys, and premature birth. The impact of high blood pressure in pregnancy on women's health and wellbeing in the postnatal period is not well understood, along with the extent to which current postnatal services are evidence-informed and if they are meeting women's needs. This study aims to compare the postnatal health of, and the care provided to, women who had high blood pressure in pregnancy compared with women who had normal blood pressure in pregnancy.

Who can participate?
Women aged 18 or above who gave birth in any of the participating NHS foundation trusts

What does the study involve?
Eligible women are approached and provided with study information on the postnatal ward and those happy to participate are asked to complete a consent form and short (5 minute) questionnaire. Following this initial contact at about three months postnatal participating women are invited to complete a 15-minute questionnaire with questions on their physical health, mental health, their babies feeding habits and the postnatal care they received.

What are the possible benefits and risks of participating?
The study findings will be used to provide evidence on if, and how, postnatal health differs amongst women with more complex pregnancies, compared to lower risk pregnancies, and if care beyond birth is meeting these women's needs, with the view of informing revisions to current postnatal services.

Where is the study run from?
1. King's College Hospital NHS Foundation Trust (UK)
2. Kingston Hospital NHS Foundation Trust (UK)
3. Ashford and St. Peter's Hospitals NHS Foundation Trust (UK)
4. Chelsea and Westminster Hospital NHS Foundation Trust (UK)
5. St George's University Hospitals NHS Foundation Trust (UK)
6. Manchester University NHS Foundation Trust (UK)
7. Salisbury NHS Foundation Trust (UK)

8. Lewisham and Greenwich NHS Trust (UK)
9. University Hospitals Coventry & Warwickshire NHS Trust (UK)
10. Western Sussex Hospitals NHS Foundation Trust (UK)
11. Croydon Health Services NHS Trust (UK)
12. Oxford University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
June 2018 to September 2020

Who is funding the study?
1. NIHR CLAHRC South London (UK)
2. NIHR Academy (UK)

Who is the main contact?
Dr Danielle Ashworth
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
249428

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
40501

Study information

Scientific Title
Postnatal health and care following hypertensive disorders in pregnancy: a prospective cohort study

Acronym
BPiPP

Study objectives
1. Do women with hypertensive disorders in pregnancy experience greater postnatal physical and psychological morbidity compared to women with normal blood pressure in pregnancy?
2. Does the extent and characterisation of postnatal morbidity differ between women with hypertensive disorders in pregnancy and women with normal blood pressure in pregnancy?
3. Do women with hypertensive disorders in pregnancy receive additional postnatal care (contacts and content in line with relevant NICE guidance) compared to women with normal blood pressure in pregnancy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - South East Research Ethics Committee, Barlow House 3rd Floor 4 Minshull Street Manchester M1 3DZ, Tel: +44 (0)207 104 8014, +44 (0)207 104 8002, Email: nrescommittee.london-southeast@nhs.net, 21/12/2018, ref: 18/LO/2084

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions

Eligible women will be approached and provided with study information on the postnatal ward and those happy to participate will be asked to complete a consent form and short (5 minute) questionnaire. Following this initial contact at approximately 3 months postnatal participating women will be invited to complete a 15 minute questionnaire, with questions included on their: physical health, mental health, their babies feeding habits and the postnatal care they received. BPiPP study findings will be used to provide evidence on if, and how, postnatal health differs amongst women with more complex pregnancies, compared to lower risk pregnancies, and if care beyond birth is meeting these women's needs, with the view of informing revisions to current postnatal services.

Intervention Type
Other

Primary outcome measure
Co-primary outcomes for research question 1:
1. Depressive symptoms, measured using the Edinburgh Postnatal Depression Score (EPDS) questionnaire (mean and threshold scores ≥13 - standard cut-off score recommended when screening for probable major depression), at 3 months postnatal
2. Health status, measured using the EuroQol Group five dimension (EQ-5D) questionnaire (mean score on the vertical visual analogue scale score), at 3 months postnatal

Primary outcomes for research question 2:
Presence and severity of morbidities measured from patient reported study survey responses at 3 months postnatal

Primary outcome for research question 3:
Women's opinion of their postnatal care contacts and content and measures of NICE guidance adherence measured from patient reported study survey responses at 3 months postnatal

Secondary outcome measures
Patient reported study survey responses at 3 months postnatal will also capture:
1. Other physical and psychological morbidity outcomes (including EQ-5D level per domain)
2. Re-admission rates
3. Breastfeeding uptake and duration rates
4. Mean number of visits/contacts with NHS services

Overall study start date
01/06/2018

Completion date
30/09/2020

Eligibility

Key inclusion criteria
1. Women who gave birth in any of the participating NHS foundation trusts
2. Women who gave birth at > = 20+0 weeks gestation
3. Women aged 18 or above
4. Women able to provide informed consent
5. Study participants unable to compete questionnaires due to lack of English fluency will be

offered use of translation facilities used in clinical practice at each site
6. Study participants who experience a neonatal death between baseline and follow up questionnaire completion will be contacted to ask if they would like to continue participating in BPiPP or withdraw

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 1000; UK Sample Size: 1000

Total final enrolment
1829

Key exclusion criteria
1. Women who gave birth in any non-participating NHS foundation trusts
2. Women who gave birth at < 20+0 weeks gestation
3. Women under 18 years old
4. Women unable to provide informed consent

Date of first enrolment
06/02/2019

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Ashford and St. Peter's Hospitals NHS Foundation Trust
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
King's College Hospital NHS Foundation Trust
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Kingston Hospital NHS Foundation Trust
Kingston Hospital
Galsworthy Road
Kingston upon Thames
United Kingdom
KT2 7QB

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
London
United Kingdom
TW7 6AF

Study participating centre
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Salisbury NHS Foundation Trust
Salisbury

United Kingdom
SP2 8BJ

Study participating centre
Lewisham and Greenwich NHS Trust
London
United Kingdom
SE18 4QH

Study participating centre
University Hospital of Coventry and Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Western Sussex Hospitals NHS Foundation Trust
Chichester
United Kingdom
PO19 6SE

Study participating centre
Croydon Health Services NHS Trust
530 London Road
Croydon
Surrey
United Kingdom
CR7 7YE

Study participating centre
University of Oxford NHS Foundation Trust
John Radcliffe Hospital
Headley Way
Oxford
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Sponsor information

Organisation
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Sponsor type
University/education

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

Organisation
Guy's & St Thomas' Foundation NHS Trust

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR CLAHRC South London

Funder Name
NIHR Academy

Results and Publications

Publication and dissemination plan
Planned dissemination of study findings through conventional academic outputs including publication in peer reviewed journals and academic conferences in addition to via websites of collaborating hospitals and appropriate groups such as support groups and charities. Study participants requesting a copy of the study results will be provided with a summary report.

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository MedSciNet. CI, study coordinator, PIs and recruiting research staff will have access to the BPiPP database. Consent from participants will be obtained and all participants will be identified by a unique study ID.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		05/04/2022	05/05/2022	Yes	No
HRA research summary			28/06/2023	No	No