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OPTIMUM: Optimising titration and monitoring of maternal blood pressure

Submission date
04/07/2016

Recruitment status
No longer recruiting

Registration date
04/07/2016

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Pre-eclampsia is a condition which affects pregnant women, and can put both mother and baby at risk. The warning signs of pre-eclampsia include high blood pressure and protein in the urine. Around 10-15% of women develop high blood pressure during pregnancy. If not treated, pre-eclampsia can lead to seizures, kidney and blood clotting problems in the mother. For babies, it can lead to low birth weight and an increased risk of dying before birth. Treatment is usually in the form of blood pressure lowering drugs. Up to 10% of women have existing chronic hypertension (long-term high blood pressure) or develop hypertension (gestational hypertension) in pregnancy. This puts them at a higher risk of developing pre-eclampsia than those without chronic high blood pressure. Because of this, their blood pressure needs to be closely monitored and managed via more frequent antenatal clinic visits. Despite more frequent monitoring however, women's blood pressure can rise between these visits, putting mother and baby at risk. One possible solution to this problem is for the women to keep track of their blood pressure at home (self-monitoring). This could help to identify rising blood pressure sooner, so that it can be brought to the attention of their care team. This could lead to earlier diagnosis and treatment to prevent complications developing. Care teams would be able to use the more frequent blood pressure readings to make better and timelier treatment decisions. For example, by raising or lowering blood pressure medication as needed. This could lead to improved health outcomes for mothers and their babies, and may prove to be a cost-effective way to improve their care. The aim of this study is to conduct a small study looking at whether it is acceptable to pregnant women with high blood pressure to monitor their blood pressure at home, and to work out whether it is feasible to conduct a larger scale study.

Who can participate?
Pregnant women with high blood pressure during pregnancy (either long-term or due to pregnancy).

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard care alone, which involves attending antenatal clinic visits to have their blood pressure measured. Those in the second group also receive standard care as well as monitoring their blood pressure at home. The women are taught how to use a home blood pressure monitor and

asked to measure it every day and record the results in a diary and/or send results via text of the study App. They are also given advice about any action they should take if their blood pressure becomes too high or too low. Participants in both groups attend routine clinical visits at 20, 28, and 34 weeks pregnancy, and 6 weeks after they have had their baby. At these visits, blood pressure measurements are taken and questionnaires about quality of life and medication use are completed. Women who have been monitoring their blood pressure also provide their self-monitoring results at these visits.

What are the possible benefits and risks of participating?
There are no direct benefits to participants taking part in this study, although the study will provide information about how blood pressure self-monitoring could help improve the health of women with high blood pressure in pregnancy. This could lead to fewer complications during pregnancy, protecting the health of both mother and baby. All women in the study will receive at least usual care, so there is no risk from missing out on any standard clinical care. No direct risks for those women self-monitoring blood pressure at home are expected as measuring blood pressure is a safe procedure. Women will be counselled how to correctly measure their blood pressure using the provided monitors and when and how to contact clinical teams if they have low or high blood pressure readings. It is possible that blood pressure self-monitoring may increase anxiety in participants but previous work by the study team in the pregnant population has found this to be very uncommon.

Where is the study run from?
1. The Women's Centre, John Radcliffe Hospital (UK)
2. St Thomas' Hospital Maternity Services (UK)
3. New Cross Hospital Maternity Services (UK)
4. King’s College Hospital (UK)

When is the study starting and how long is it expected to run for?
April 2015 to October 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Louise Pealing
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20090

Study information

Scientific Title
Blood pressure self-monitoring for the management of women during pregnancy with chronic hypertension: a feasibility study

Acronym
OPTIMUM

Study objectives
The aim of this study is to:
1. Assess the feasibility and acceptability of pregnant women with chronic hypertension monitoring their own blood pressure
2. Identify the most appropriate 'outcome measures' for blood pressure control to use in a larger trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands – Nottingham 2 Research Ethics Committee, 28/10/2015, ref: 15/EM/0490
Substantial Amendment 1: REC approval: 27/09/2016, HRA approval: 06/10/2016
Substantial Amendment 2: REC approval: 20/12/2016, HRA approval: 20/12/2016

Study design
Randomized; Interventional; Design type: Diagnosis, Complex Intervention, Management of Care, Active Monitoring

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Specialty: Reproductive health and childbirth, Primary sub-specialty: Reproductive health and childbirth (migration)

Interventions
Pregnant women with chronic hypertension will be randomised 2:1 intervention to usual care using a secure web-based system, with allocation stratified for study site.

Control group: Participants receive usual antinatal care alone.

Intervention group: Participants receive usual antenatal care and blood pressure self-monitoring at home in the management of chronic hypertension during pregnancy. This involves women being asked to measure their own blood pressure once per day at the same time each day, taking two readings, using an automated blood pressure machine (microlife WatchBP home) validated for use in pregnancy and pre-eclampsia. They will be asked to measure their own blood pressure from time of enrolment until delivery. If women are admitted to hospital during their pregnancy they are asked to continue to monitor their own blood pressure if they are able and this is acceptable to them. Women will be asked to record these blood pressure readings in a diary and bring them to their antenatal consultations so that their clinical team can use them in making treatment decisions. Women will be given a protocol to follow advising how and when to contact for clinical advice in the event of recording any high or low blood pressure readings.

Participants in both groups attend antenatal visits at 20, 28 and 34 weeks gestation and 6 weeks postnatal for blood pressure monitoring and completion of questionnaires.

Added 16/06/2017:
In addition women with gestational hypertension will be asked to text or use a study App to submit their home blood pressure readings to the research team, but also retain the option of continuing to use the blood pressure diary to record these readings.

Intervention Type
Other

Primary outcome measure
1. Recruitment rate is determined at the end of the study period by recording the number of participants recruited per site per month, including as proportion of those who were approached and eligible
2. Loss to follow up is determined at the end of the study period by recording the number lost to

follow-up after delivery/number of participants recruited
3. Withdrawal rate is determined at the end of the study period by recording the number of participants withdrawing consent/number of participants recruited
4. Adherence and persistence with BP self-monitoring protocol is determined as the proportion of intervention participants completing no home BP measurements (total and by week) at the end of the study period
5. Acceptability of randomisation is determined at the end of the study period by recoridng the proportion of participants citing randomisation as reason for non-participation and the proportion in usual care arm starting home BP monitoring post-randomisation

Secondary outcome measures

1. Blood pressure control measured using:
1.1. Highest systolic blood pressure recorded between randomisation and delivery, excluding day of delivery
1.2. Average systolic blood pressure recorded between randomisation and delivery, excluding day of delivery (calculated using trapezium method applied to area under the curve)
1.3. Proportion developing systolic BP >=150 mmHg, and diastolic BP >=100 mmHg, recorded between randomisation and delivery, excluding day of delivery
2. Antihypertensive medication adherence measured using:
2.1. MARS and BMQ questionnaire score differences measured at 20, 28 and 34 weeks gestation
2.2. Defined Daily Dose of oral antihypertensive medication measured at 20, 28 and 34 weeks gestation
3. Maternal outcomes including:
3.1. Morbidity or mortality (pre-eclampsia, eclampsia, intracranial haemorrhage/infarct, myocardial ischaemia/infarction, intubation, pulmonary oedema, hepatic dysfunction, acute kidney injury, neurological dysfunction other than stroke (altered GCS, blindness, hyperreflexia + clonus, severe headache +hyperreflexia, persistent visual scotoma), disseminated intravascular coagulation, HELLP syndrome (haemolysis, elevated liver enzymes, low platelets), placental abruption, post-partum haemorrhage), all assessed on final maternal discharge after delivery
3.2. Gestation at delivery (assessed at delivery)
3.3. Mode of delivery (assessed at delivery)
3.4. Indication for delivery (assessed at delivery
4. Perinatal outcomes including:
4.1. Neonatal mortality or stillbirth (assessed at time of death)
4.2. Neonatal morbidity (including admission to neonatal unit: LDC, HDU, ICU; respiratory distress syndrome, need for ventilator support) all assessed on discharge of infant
4.3. Prematurity and small-for-gestational-age (assessed at delivery)
5. Health resource use outcomes including:
5.1. Number and cost of clinical contacts (antenatal attendances to clinic and day unit) and admissions and their timing for out-of-range BP readings and all-causes (assessed on maternal discharge)

Continuous ethnography is conducted during the trial.

Qualitative and experiential outcomes
1. How self-monitored BP readings are used in the management of chronic hypertension during pregnancy. Focused ethnographic study observing antenatal clinic and DAU/MAU consultations (assessed throughout pregnancy)
2. The experiences of the participants and clinicians involved in the study, measured using validated antenatal and postnatal health questionnaires (STAI, EQ-5D-5L and Little's) and semi-structured interviews with women and clinicians in the postnatal period

Overall study start date
01/04/2015

Completion date
31/10/2018

Eligibility

Key inclusion criteria
1. Women with chronic hypertension (defined as sustained diastolic BP≥90 mmHg and/or systolic BP≥140 mmHg, present at booking or before 20 weeks gestation, or receiving treatment outside pregnancy and/or at time of referral)
2. Recruited at booking- 23+6 weeks gestation
3. Viable singleton pregnancy
4. Willing to be randomised
5. Able to give informed written consent
6. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 160; UK Sample Size: 160

Total final enrolment
158

Key exclusion criteria
1. Unwilling to self-monitor
2. Insufficient understanding of the study
3. Confirmed super-imposed pre-eclampsia (as defined by the International Society for the Study of Hypertension in Pregnancy (ISSHP) 2014 statement) before recruitment

Date of first enrolment
09/12/2015

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
The Women's Centre
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
St Thomas' Hospital Maternity Services
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
New Cross Hospital Maternity Services
Wolverhampton Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
King’s College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Sponsor information

Organisation
University of Oxford Clinical Trials and Research Governance Team

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

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 of publish results from both the quantitative and qualitative analysis of this trial in peer-reviewed journals at the end of the trial at the end of 2018. Public dissemination of the results will also occur through the relevant on-line information sites such as womens' health and pregnancy charities.

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2019	16/10/2019	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Secondary analysis	28/05/2021	18/08/2023	Yes	No