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Breastfeeding and blood Pressure patterns in MOthers with recent hypertensive coMplications of pregnancy - BP-MOM Study

Submission date
18/01/2019

Recruitment status
No longer recruiting

Registration date
29/01/2019

Overall study status
Completed

Last Edited
14/10/2022

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Women with hypertensive (high blood pressure) disorders of pregnancy including preeclampsia and gestational hypertension are at increased risk for later cardiovascular (heart) disease. Breastfeeding may lower maternal blood pressure and other cardiovascular risk factors, and interventions designed to improve mothers' breastfeeding self-efficacy (i.e., confidence about breastfeeding) have been helpful for healthy postpartum women. However, such breastfeeding support interventions have not yet been tested specifically in women who have had hypertensive disorders of pregnancy, a group who may benefit substantially from breastfeeding. This study tests a nurse-led self-efficacy based breastfeeding intervention in women with hypertensive disorders of pregnancy, to measure whether the intervention is feasible in this population and whether it improves breastfeeding rates and/or lowers maternal blood pressure.

Who can participate?
Women at least 18 years old who have been diagnosed with a hypertensive disorder of pregnancy (preeclampsia or gestational hypertension), have given birth to a live-born single infant delivered at 34 weeks gestation or later, who intend to breastfeed and have started breastfeeding before hospital discharge, speak and understand English or French, and have access to a telephone.

What does the study involve?
Participants are randomly allocated to receive either usual postpartum care, or usual postpartum care plus additional breastfeeding support. Additional breastfeeding support will include the nurse-led intervention designed to improve women's confidence about breastfeeding.

What are the possible benefits and risks of participating?
Participants who receive additional breastfeeding support may benefit from the nurse-led breastfeeding intervention. The study involves collection of test results from blood draws that are part of routine postpartum care. Blood draws may cause temporary discomfort, minor bleeding, light-headedness, and rarely, fainting.

Where is the study run from?
McGill University Health Centre (MUHC), Montreal (Canada)

When is the study starting and how long is it expected to run for?
May 2018 to December2021

Who is funding the study?
The study is supported by startup funds of the principal investigator, Natalie Dayan

Who is the main contact?
Natalie Dayan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2019-4726

Study information

Scientific Title

Pilot randomized trial of a nurse-led self-efficacy based breastfeeding intervention in women with hypertensive disorders of pregnancy

Acronym
BP-MOM

Study objectives
The trialists hypothesize that a self-efficacy based breastfeeding intervention in women with hypertensive disorders of pregnancy will be feasible in this population. They further hypothesize that there will be a trend toward protective effects on maternal health as measured by blood pressure, weight, and continued breastfeeding, at 6 months postpartum, with continued but dampened protective effects at 12 months postpartum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of the McGill University Health Centre (MUHC), 2155 Guy Street, 2nd floor, Montreal, Quebec, H3H 2R9, Tel: +1 (0)514 934 1934 ext. 36077, Email: sheldon.levy@muhc.mcgill.ca, 20/11/2018, protocol number: 2019-4726

Study design
Single-centre pilot randomized open-label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Hypertensive disorders of pregnancy, including preeclampsia and gestational hypertension

Interventions
Nurse-led breastfeeding enhancing intervention, including a maternal assessment followed by the provision of tailored lactation management strategies to enhance breastfeeding self-efficacy and support exclusive breastfeeding. Participants are randomized 1:1 to the intervention or usual postpartum care.

Intervention Type
Behavioural

Primary outcome measure

Feasibility, including recruitment, retention and participant satisfaction with the intervention:
1. Recruitment rate is defined as the number of eligible women who consented/number of eligible women who were approached, calculated at baseline
2. Retention rate is defined as the number of women who complete 12-month follow-up for the study/all women who consent to participate, calculated at 12-month follow-up
3. Participant satisfaction with the breastfeeding intervention will be measured using a self-administered questionnaire that includes quantitative and qualitative items on participants' satisfaction with the support received from the study nurse, measured at 3 months and 6 months postpartum

Secondary outcome measures
1. Exclusive breastfeeding assessed by self-report at 6 months and 12 months postpartum
2. Total breastfeeding duration assessed by self-report at 6 months and 12 months postpartum
3. Blood pressure measured by the study nurse at 12 months postpartum
4. Use of anti-hypertensive medication as ascertained from the participant's medical chart at 12 months postpartum

Overall study start date
01/05/2018

Completion date
01/12/2021

Eligibility

Key inclusion criteria
1. Age >18 years
2. Diagnosis of hypertensive disorder of pregnancy (preeclampsia or gestational hypertension)
3. Singleton live birth delivered at >34 weeks gestation
4. Mother intends to breastfeed and breastfeeding initiated before hospital discharge
5. Patient speaks and understands English or French
6. Patient has telephone access

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
75

Total final enrolment
45

Key exclusion criteria
1. Maternal contraindication to breastfeeding
2. Maternal condition that interferes with breastfeeding
3. Neonatal condition that interferes with breastfeeding
4. Infant born before 34 weeks gestation
5. Maternal ICU admission lasting >24 hours

Date of first enrolment
02/01/2019

Date of final enrolment
21/11/2019

Locations

Countries of recruitment
Canada

Study participating centre
McGill University Health Centre
1001 Boulevard Décarie
Montreal
Canada
H4A 3J1

Sponsor information

Organisation
McGill University Health Centre

Sponsor details
1001 Boulevard Décarie
Montreal
Canada
H4A 3J1

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04cpxjv19

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
McGill University Health Centre (startup funds)

Results and Publications

Publication and dissemination plan
The study protocol will be available on request. The trialists will disseminate their findings to:
1. Members of the general public via press releases to local, national, and international media organizations, and via commercial and community organizations dedicated to women's health such as Nourri-Source, La Leche, the Preeclampsia Foundation, and Johnson & Johnson
2. Clinicians involved in perinatal care, e.g., knowledge users from the Society of Obstetricians and Gynaecologists of Canada (SOGC), Canadian Association of Women's Health, and Canadian Lactation Consultant Association
3. Policy makers, in particular the World Health Organization and American Academy of Pediatrics as they relate to breastfeeding recommendations, and the SOGC, Hypertension Canada, and the Canadian Cardiovascular Society as they relate to hypertension and cardiovascular risk management

Intention to publish date
30/12/2022

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date