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Does supplementation of extra Magnesium daily to first time pregnant healthy women prevent blood pressure increase during pregnancy?

Submission date
23/04/2018

Recruitment status
No longer recruiting

Registration date
27/04/2018

Overall study status
Completed

Last Edited
16/07/2018

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
High blood pressure during pregnancy is a risk factor for developing pre-eclampsia (high blood pressure, causing large amounts of protein in urine or other organ dysfunction), which can lead to onset of seizures, known as eclampsia (E). It affects approximately 6-8% of all pregnant women.
A blood pressure of 140/90 mmHg is defined as gestational hypertension (HT). The cause of HT is depends on a number of factors, such as but nulliparity (never given birth before), obesity, stress, genetics, high maternal age, multiple pregnancy, diabetes, thrombophilia (increased tendency for blood clotting), kidney disease, chronic HT and nutritional deficiency.
When HT is accompanied by abnormal amounts of protein in the urine (proteinuria) of at least 0.3 g/day, it is defined as pre-eclampsia. Little is known about efficient preventive treatment against BP increase during pregnancy, but some study reports support the suggestion that Magnesium supplementation could have a preventive effect.
This study aims to investigate the effect of magnesium supplementation in healthy pregnant women for prevention of blood pressure increase.

Who can participate?
Pregnant women aged 18 – 40 years who have not given birth before.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive 400mg Magnesium Extra, Diasporal® supplement, taken daily. Those in the second group take a placebo (dummy pill) daily.
Participants have their blood pressure measured throughout pregnancy, and blood samples taken at weeks 12-14 and 35.
Labour and fetal outcomes are recorded from medical records at delivery.

What are the possible benefits and risks of participating?
Supplementation of magnesium during pregnancy could possibly prevent blood pressure increase in late pregnancy, which about 10% of first time pregnant women suffer from. Participants may be at risk from possible side effects such as abdominal pain, diarrhea and nausea, but none considered hazardous to the pregnant women. No negative effects have been reported regarding the fetus.

Where is the study run from?
1. Antenatal care unit (ACU) in Borås (Sweden)
2. Antenatal care unit in Alingsås (Sweden)
3. Antenatal care unit in Trollhättan (Sweden)

When is the study starting and how long is it expected to run for?
January 2014 to December 2018

Who is funding the study?
1. Lokala FoU rådet SÄS (Sweden)
2. The Research and Development Foundation at Region Halland (Sweden)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
Mg400

Study information

Scientific Title

Magnesium supplementation and blood pressure in pregnancy - a double-blind randomized multicenter study

Study objectives
The primary aim of the study is to investigate whether a daily supplementation with 400 mg Mg during pregnancy compared to a placebo group in a double-blind setting could prevent an increase of diastolic BP of at least 15 mm Hg. Secondary outcomes are comparison of biomarkers for hypertensive disorders, labour and fetal outcomes between the groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Ethics Review Board University of Gothenburg Sweden, 07/08/2014, ref: Dnr578-14

Study design
Placebo-controlled double-blind interventional multicenter study

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Blood pressure in pregnancy

Interventions
After oral and written consent, participants are randomised in a computerised double-blind procedure to receive either Mg (400 mg Magnesium Extra, Diasporal®) or placebo, taken daily. The code is not broken until all participants have given birth.
Data is collected throughout pregnancy and from medical records after delivery. There is no further patient follow up after delivery.
Blood samples are collected at gestational weeks 12–14 and 35 for analysis of IL-6, CRP, urate, cystatin C, Mg, Ca, albumin, creatinine and glomerular filtration rate (GFR). Blood pressure (BP) is measured at the ACU at 2–3 week intervals throughout the pregnancy, with the women seated with arm- and backrest support, down to Korotkoff V with a manual sphygmomanometer. BP data registered at the ACU and labour ward are collected from medical records. Records are obtained on gestational length at birth, labour outcomes including excessive bleeding >1000 ml, instrumental delivery, duration of active labour, and fetal outcomes including Apgar score at five minutes, pH in the arterial umbilical cord, birth weight and need of care at a neonatal intensive care unit (NICU).

Intervention Type
Supplement

Primary outcome(s)
Blood pressure is measured using manual sphygmomanometer at 2-3 week intervals throughout the pregnancy, and obtained from medical records at labour.

Key secondary outcome(s))

1. Biomarkers for hypertensive disorders (IL-6, CRP, urate, cystatin C, Mg, Ca, albumin, creatinine and glomerular filtration rate (GFR) are analysed from blood samples at gestational weeks 12-14 and 35.
2. Labour and foetal outcomes (gestational length at birth, excessive bleeding >1000 ml, instrumental delivery, duration of active labour, Apgar score at five minutes, pH in the arterial umbilical cord, birth weight and need of care at a neonatal intensive care unit) are collected from medical records after delivery.

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Nulliparity
2. No regular medication
3. Normotension
4. Singleton pregnancy
5. Maternity age >18 years and < 40 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Age <18 or >40 years
2. Multiple pregnancy
3. Trombophilia
4. Previous labour
5. Diabetes
6. Chronic HT
7. Kidney disease
8. Heart disease
9. Regular medication
10. History of cardiac arrhythmia
11. Heredity of sudden cardiac arrest

Date of first enrolment
15/08/2014

Date of final enrolment
15/01/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Antenatal care unit (ACU) in Borås
Bryggaregatan 5
Borås
Sweden
503 38

Study participating centre
Antenatal care unit in Alingsås
Oscarsgatan 9 B
Alingsås
Sweden
441 83

Study participating centre
Antenatal care unit in Trollhättan
Drottninggatan 38 A
Trollhättan
Sweden
461 32

Sponsor information

Organisation
Protina Pharmazeutische GmbH

Funder(s)

Funder type
Research council

Funder Name
Lokala FoU rådet SÄS (Diarienummer: VGFOUSA-420031)

Funder Name
The Research and Development Foundation at Region Halland

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/05/2018		Yes	No