ISRCTN15485068 https://doi.org/10.1186/ISRCTN15485068

The effect of oral high-micronutrient nutritional supplements on lipid profile in underweight hypertensive pregnant women

Submission date
05/03/2018

Recruitment status
No longer recruiting

Registration date
21/04/2018

Overall study status
Completed

Last Edited
03/05/2024

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 one of the major complications of pregnancy. The occurrence of pre-eclampsia is high in Pakistan and as a developing country we are facing problem of under nutrition. Nutritional supplements are effective at promoting weight gain and increasing energy intake, lSo keeping in mind the efficacy of multiple micronutrient nutritional supplements we design this study. They promote weight gain and increase in energy intake, improves lipid profile and micronutrient status. This study aims is to determine the effect of multiple micronutrient nutritional supplements on cardio-metabolic biomarkers , on appetite, energy intake in pregnant women with high blood pressure and pregnancy outcome and blood sugar and troponin levels in their babies .

Who can participate?
Underweight females aged 15-35 years after 20 weeks gestation with their first pregnancy, experiencing symptoms of pre-eclampsia

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a nutritional supplement once daily, and dietary counseling until 6 months after delivery. Those in the second group only receive dietary counseling.
Both groups attend regular pre-birth appointments and take any prescription advised by their doctor.
Participants have blood and urine samples taken before the intervention, at delivery and at 6 months after delivery.
The birth outcomes are recorded for mother and baby, and the baby has blood samples analyzed at delivery and 6 months after.

What are the possible benefits and risks of participating?
The participants may benefit from nutrition supplements to improve their nutritional status. There is no major risk for participants and their babies.

Where is the study run from?
1. Lady Reading Hospital Peshawar (Pakistan)
2. Khyber teaching Hospital Peshawar (Pakistan)
3. Hayat Abad Medical Complex Peshawar (Pakistan)

When is the study starting and how long is it expected to run for?
November 2017 – June 2020 (updated 23/07/2019, previously: November 2023)

Who is funding the study?
1. Khyber Medical University Peshawar (Pakistan)

Who is the main contact?
Dr Nabila Sher Mohammad (Public)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of multiple micronutrient nutritional supplementation on cardio-metabolic biomarkers of pre-eclamptic women: a randomized controlled trial

Study objectives
The multiple micronutrient nutritional supplements may have beneficial effect on the cardio metabolic biomarker in preeclampsia and decrease the incidence of cardio metabolic disorders in the women having preeclampsia. It may also improve the outcome of pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee of Khyber Medical University Peshawar Pakistan, 27/10/2016, ref: DIR/KMU-EB/EN/000314

Study design
Single blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Preeclampsia

Interventions

Participants are identified from antenatal units of tertiary care hospitals of Peshawar and study aims and objectives are explained to them. Each participant is screened for eligibility criteria and if eligible provide informed consent.

Participants are randomly divided into intervention and control groups by computerized randomization using free software (Research randomiser version 3).
Those in the intervention group receive one 75 gram sachet of MAMTA daily (World Food Programme nutritional supplement for underweight pregnant and lactating women) and dietary counselling from above 20 weeks gestation until 6 months after delivery.
Those in the control group receive dietary counselling and both groups attend their regular antenatal visits and any prescription advised by their gynecologists.

After detailed history, each participant comes after overnight fasting at metabolic suit for first experimental trial day and sample collection. The baseline blood sample of 5ml and urine sample is collected under aseptic technique. Blood is processed and stored at -80 oC in cold storage of KMU Lab while urine is used immediately for urinary protein using dipstick method.
Data on appetite questionnaire and a 5-ml blood sample is obtained on fasting, 30 min after supplementation and placebo drinks, 30 min after breakfast and lunch to see short term impact of supplementation on blood glucose. Insulin levels and insulin resistance is calculated by HOMA (homeostasis modal assessment: fasting glucose X fasting insulin/22.5). Buffet breakfast is served after 60 minutes and lunch after 270 min to each participant. Appetite questionnaires are marked at 0, 60, 90, 210, 240, 300, and 330 min. Both the groups return home with information about their nutritional supplements (inlcuding routinly prescribed supplements by their doctor during their antenatal checkups if applicable). For those in the intervention group, nutritional supplements are provided after 15 days, and consumption of LNS-PLW and routine prescribed supplements is checked during antenatal check ups.
The second blood and urine sample is collected at the time of delivery from each participant during their post delivery stay in hospital which is routinely 12 h in case of normal vaginal delivery. Baby cord blood is collected for hr-troponin, blood glucose levels and IGF as baseline. Both the groups are sent home with information about their nutritional supplements and diet plan and for their postnatal follow-ups.
The third blood and urine samples are obtained from all the participants and the second blood sample from their child after 6 months of follow up.

Participant blood is analysed for cardiac biomarkers (total cholesterol, triglyceride, high density lipoprotein, low density lipoprotein, very low density lipoprotein, Apo A, Apo B, Lpa) and for metabolic biomarkers (fasting blood glucose, Hba1c, insulin levels, insulin resistance, insulin growth factor). Apo A , Apo B and LPA are measured using electrochemiluminescence technique by Modular E411 Roche. Insulin resistance is measured using formula HOMA (IR) = Fasting glucose * Fasting insulin/22.5. Urine Albumen is detected by dipstick method. Total cholesterol, triglyceride, high density lipoproteins, low density lipoproteins and very low density lipoproteins are measured by Cobas C11. Insulin, Insulin growth factor and troponin are analyzed by ELISA.

Intervention Type
Supplement

Primary outcome measure
1. Lipid profile is analysed from a blood sample by using cobas C3 analyzer at baseline, delivery and 6 months post-delivery.
2. Apo A , Apo B and LPA measured from a blood sample using electrochemiluminescence technique by Modular E411 Roche at baseline, delivery and 6 months post-delivery.

3. Insulin and insulin growth factor is analysed from a blood sample by ELISA at baseline, delivery and 6 months post-delivery.
4. Insulin resistance is measured using formula (HOMA (IR) = Fasting glucose *Fasting insulin/22.5) at baseline, delivery and 6 months post delivery.
5. Urine Albumen is detected using dipstick method at baseline, delivery and 6 months post-delivery.
6. Patient outcome measures are the mode of delivery (normal vaginal delivery, assisted vaginal delivery, cesarean section) and (full term, premature, stillbirth etc) assessed by reviewing patient notes from the hospital and their medical test at baseline on time of recruitment after 20 weeks of gestation , at their stay in hospital on time of delivery from the mother and their baby and 6 months after delivery from both mother and babies.
7. Hr-troponin and blood glucose levels are analysed from baby cord blood at delivery (baseline) and 6 months.

Secondary outcome measures
1. Energy intake is calculated by win diet 2005 software after the intake of supplements.
2. Appetite is measured using validated questionnaires after the intake of supplements.
3. Compliance to the supplement is measured by the empty sachet and leftovers
4. Satisfaction is measured using the following questions:
4.1. Are you satisfied by MAMMTA?
4.2. Will you be happy to use MAMMTA in your next pregnancy?

Overall study start date
01/11/2017

Completion date
06/12/2019

Eligibility

Key inclusion criteria
1. Primigravida after 20 weeks of gestation with the sign and symptoms (hypertension, proteinuria and edema) of preeclampsia.
2. Female aged 15 to 35 years.
3. Under-weight preeclamptic with BMI = <18.5 kg/m2 at first antenatal visit from antenatal record.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
15 Years

Upper age limit
35 Years

Sex

Female

Target number of participants
The number of participants needed to complete the study was 44 (22 in each group). To account for a potential drop-out rate of 40%, the investigators aimed to recruit 60 participants.

Total final enrolment
48

Key exclusion criteria
1. Normal pregnant women
2. Past history of hypertension, essential hypertension, diabetes mellitus, renal disorders, liver disorders.
3. Previously on long medications
4. Any history of GIT disease, surgery or any eating disorder like bulimia nervosa, anorexia nervosa and purging disorders.

Date of first enrolment
15/04/2018

Date of final enrolment
29/08/2018

Locations

Countries of recruitment
Pakistan

Study participating centre
Khyber Teaching Hospital
Antenatal Unit
University Road
Peshawar
Pakistan
25000

Study participating centre
Lady Reading Hospital
Antenatal Unit
Hospital Road
Peshawar
Pakistan
25000

Study participating centre

Hayatabad Medical Complex
Antenatal Unit
Phase 4
Peshawar
Pakistan
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Study participating centre
Khyber Medical University
Antenatal Unit
Hayatabad
Peshawar
Pakistan
25000

Sponsor information

Organisation
Khyber Medical University

Sponsor details
Phase 5
Hayatabad
Peshawar
Pakistan
25 000

Sponsor type
University/education

ROR
https://ror.org/00nv6q035

Funder(s)

Funder type
University/education

Funder Name
Khyber Medical University

Results and Publications

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

Intention to publish date
01/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nabila Sher. All the data will be kept in hard form in the locked cabinet of department of Biochemistry Institute of Basic Medical Sciences Khyber Medical University Peshawar and in soft form with the main researcher for five years after completing the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/07/2021	20/12/2021	Yes	No
Results article		10/01/2024	03/05/2024	Yes	No