

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

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Registration date 21/04/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/05/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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, (So 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

Contact name

Dr Nabila Sher Mohammad

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Effects of multiple micronutrient nutritional supplementation on cardio-metabolic biomarkers of pre-eclampsic 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

Study type(s)

Prevention

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 (including routinely 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 $HOMA (IR) = \text{Fasting glucose} * \text{Fasting insulin} / 22.5$. 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(s)

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 $(HOMA (IR) = \text{Fasting glucose} * \text{Fasting insulin} / 22.5)$ 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.

Key secondary outcome(s)

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?

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

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

15 years

Upper age limit

35 years

Sex

Female

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

ROR

<https://ror.org/00nv6q035>

Funder(s)

Funder type

University/education

Funder Name

Khyber Medical University

Results and Publications

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