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The effect of Oral High Energy Nutritional Supplements on appetite, pregnancy and fetal outcomes in underweight women during their first pregnancy

Submission date
05/03/2018

Recruitment status
No longer recruiting

Registration date
27/03/2018

Overall study status
Completed

Last Edited
25/10/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
It has been shown that high energy nutritional supplements are very effective in treating malnutrition in developing countries. They promote weight gain and increase in energy intake, improves lipid profile and micronutrient status. This study aims to determine the effect of high-energy, nutritional supplements on appetite, energy intake, lipid profile and micronutrient status of women who become pregnant for the first time.

Who can participate?
Women aged 15-45 years who are pregnant for the first time.

What does the study involve?
After taking consents from ethical committee of KMU & the respected tertiary care hospital, women will be selected according to inclusion criteria. The information/ protocols of the study will be discussed in detail with the participants and the hospital authorities. Participants will be randomly allocated to one of two groups either receiving the supplements or placebo,which will be delivered by the main investigator on weekly basis,& empty sachets of supplements will be collected to check the compliance of the participants.The participants will be asked to make three visits ,a baseline trial,week 16 of gestation & a post natal visit On baseline trial day,the participants will be asked to visit the clinical trial room of KMU in fasting state, fasting state blood samples will be collected & appetite questionnaire will be marked& then, they will be provided with supplement/placebo & again blood samples collected & appetite questionnaires will be marked 30 minutes after supplementation and then with ad libitum buffet breakfast and ad libitum buffet lunch at specific time intervals. Blood samples will be taken &Appetite questionnaires will be marked at 30, 60, 120, 210, 270 minutes after supplementation . The participants will be asked to consume supplements/placebo in addition to their habitual diet & antenatal treatment.Records of their antenatal visits & treatment plus any complication will be kept.Nutritional counselling will be provided to the participants.Then fasting blood samples will be taken during week 16 of gestation & postnatally.The outcome of the pregnancy will be

recorded & cord blood sample & colustrum sample will be collected & baby;s anthropometric measurement will be taken to look for the long term effect supplementation on fetal & pregnancy outcome.

What are the possible benefits and risks of participating?
There will be no major benefits or risk of participating. The information collected during this study will give a better understanding of the effect of supplementation during pregnancy. As dietary counseling is a fundamental and effective part of the treatment of malnutrition, the participants will get nutritional counseling on the completion of the study. As for risks, there might be a small bruise on skin from where the blood is taken.

Where is the study run from?
The study is run from the main tertiary care hospitals of Khyber Pakhtunkhwa province in Pakistan.

When is the study starting and how long is it expected to run for?
november 2017 to november2023

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of high energy nutritional supplements on appetite regulators, energy intake and lipid profile in underweight primigravida

Study objectives
The use of oral high energy nutritional supplements by the underweight healthy primigravida improves voluntary oral intake, appetite, appetite hormones, lipid profile and pregnancy outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration. An application has been made to the ethical approval committee of Khyber Medical University.

Study design
Single-blinded randomized placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Low weight in women who are pregnant for the first time

Interventions
After participants are recruited, written informed consent and a detailed medical history will be taken to exclude chronic illness, eating disorders, and major gastrointestinal operations. Each participant will be asked to participate in three main experimental trials conducted at baseline, 16th week of gestation and post-natally. In addition to antenatal treatment & supplements /placebo the participants will also be provided with nutritional counseling. At the beginning of

the trial, the participants will be randomly allocated to receive either a high energy nutritional supplement or placebo by computerized randomization using free software (Research Randomiser version 3). On the baseline experimental day, the participant will be requested to visit the clinical trial room at Khyber Medical University, Peshawar. Participants will be provided with 10 minutes to rest and acclimatize with the environment and then anthropometric measurements will be taken. Afterwards baseline blood samples will be collected and an appetite questionnaire will be marked. Blood samples and data on appetite will be obtained in the fasted state, 30 min after supplementation and at 60, 120, 210 and 270 min. Participants will be provided with ad libitum buffet breakfast and ad libitum lunch. A complete record of antenatal visits and routine antenatal investigations including maternal mortality, maternal anemia (Hb<10 g/dl), miscarriage (loss of pregnancy before 28 weeks of gestation), placental abruption, pre-eclampsia, mode of delivery and congenital anomalies will be maintained by the researcher. Participants will be asked to consume the supplements/placebo in addition to their habitual diet and antenatal treatments including supplements prescribed by their doctor throughout the pregnancy and one week after the delivery. The supplements will be delivered on weekly basis. The participants will be asked not to discard the empty bottles of the supplements/placebo after utilization, which will be collected in the following week in order to check the compliance. Any left over in the bottle will be recorded. Then again during the 16th week of gestation and postnatal visit fasting blood will be taken and tests will be repeated .

Intervention Type
Supplement

Primary outcome measure
1. Energy consumed during the days prior to experimental trial and during ad libitum breakfast and lunch calculated using dietary analysis software (Windiets 2005, The Robert Gordon University, Aberdeen, Scotland, UK)
2. Appetite measured using a validated appetite questionnaire at baseline, week 16 and postnatally
3. Lipid profile analyzed using Cobas C3 analyzer
4. Maternal hemoglobin, hematocrit and mean corpuscular volume measured by hematology analyzer at baseline, week 16 & potnatal visit
5. Pregnancy outcome
6. Iron, zinc and calcium levels in cord blood analyzed by atomic absorption spectrometry (AAS)
7. Iron, zinc and calcium levels in colostrum measured by Cobas 8000 Modular Analyzer

Secondary outcome measures
1. Maternal satisfaction and compliance
2. Socioeconomic data

Overall study start date
01/11/2017

Completion date
01/11/2023

Eligibility

Key inclusion criteria
1. Healthy
2. First pregnancy

3. Body mass index <18.5 kg/m2
4. Aged 15-45 years

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Female

Target number of participants
12 in each group

Key exclusion criteria
1. Major illness such as gestational diabetes mellitus, pregnancy-induced hypertension, thyroid disease or liver disease
2. Previously on any long-term medication.
3. Allergic to supplement ingredients.
4. Previous history of gastrointestinal tract anomalies, surgeries and any other eating disorders e.g. bulimia nervosa, anorexia nervosa and purging disorders

Date of first enrolment
01/04/2018

Date of final enrolment
24/01/2019

Locations

Countries of recruitment
Pakistan

Study participating centre
clinical trial room of KMU & tertiary care hospitals of khyber pukhtoon khwa
Hayatabad medical complex ,Peshawar
Khyber teaching hospital,Peshawar
Lady reading hospital,Peshawar
The woman's hospital,Peshawar
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Sponsor information

Organisation
Khyber medical university

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Sponsor type
University/education

ROR
https://ror.org/00nv6q035

Funder(s)

Funder type
Not defined

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
01/10/2023

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			01/04/2019	No	Yes
Results article		01/02/2023	21/02/2023	Yes	No
Results article		22/12/2021	28/11/2023	Yes	No
Results article		23/10/2024	25/10/2024	Yes	No