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Effects of multiple micronutrient supplements (MMS) versus iron folic acid (IFA) supplements on maternal and birth outcome: a controlled trial in Karachi, Pakistan

Submission date
03/11/2025

Recruitment status
Recruiting

Registration date
04/11/2025

Overall study status
Ongoing

Last Edited
04/11/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Anemia during pregnancy—especially when caused by low iron levels—is a serious health issue in Pakistan. It can affect a woman's physical strength, energy, and ability to make decisions, and may even increase her risk of experiencing domestic violence. This study aims to find out whether taking iron and folic acid supplements or a mix of different vitamins and minerals is more effective in improving the health of pregnant women and their babies. It also looks at how these supplements might affect women's empowerment and whether anemia is linked to domestic violence.

Who can participate?
Pregnant women in their first trimester (less than 14 weeks along) will be invited to take part in the study.

What does the study involve?
A total of 508 women will be recruited. Half will receive iron and folic acid supplements, and the other half will receive multiple micronutrient supplements. Participants will be asked to complete questionnaires about their background, experiences with domestic violence, and feelings of empowerment. Their blood will be tested for hemoglobin levels early in pregnancy and again in the third trimester. Information about their babies' health will be collected after birth.

What are the possible benefits and risks of participating?
Participants may benefit from improved health during pregnancy and better outcomes for their babies. The study could also help raise awareness about the importance of nutrition and women's empowerment. Risks are expected to be minimal, but may include discomfort from blood tests or sensitive questions in the surveys.

Where is the study run from?
Baqai Medical University in Pakistan.

When is the study starting and how long is it expected to run for?
September 2025 to December 2026.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Shagufta Naseer, shaguftanaseer@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effects of multiple micronutrient supplements (MMS) versus iron folic acid (IFA) supplements on maternal and birth outcome: a controlled trial in Karachi, Pakistan

Study objectives

Primary Objectives:
1. To compare the frequency of maternal iron deficiency anemia among women receiving Iron Folic Acid (IFA) versus Multiple Micronutrient Supplement (Multiple Micronutrient Supplement) initiated in the first trimester (<14 weeks of gestation)
2. To compare the incidence of preterm birth, low birth weight and early neo-natal mortality between IFA and Multiple Micronutrient Supplement group initiated in the first trimester (<14 weeks of gestation) in a few hospitals of Karachi.

Secondary Objectives:
1. To determine the association between iron deficiency anemia, domestic violence and women's empowerment status.
2. To investigate how domestic violence and women's empowerment status affect compliance with Iron and Folic Acid (IFA) or Multiple Micronutrient Supplementation (MMS) and their subsequent effects on pregnancy and neonatal outcomes i.e. preterm birth, low birth weight and early neo natal mortality.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/08/2025, Baqai Medical University (51, Deh Tor, Gadap Road, Super Highway, Karachi, 75340, Pakistan; +92 330 8180823; registrar.secretriat@baqai.edu.pk), ref: BMU-IREB /16-2025/002

Study design
Multi center inferiority interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Anemia, low birth weight baby, early neo natal mortality

Interventions
IFA: In this interventional arm, women will be provided with Iron and Folic Acid (IFA) supplementation with a daily dose containing elemental iron of 60 milligrams and folic acid of 400 micrograms.

MMS: In this interventional arm, women will be provided with United Nations International Multiple Micronutrient Antenatal Preparation (UNIMMAP). The UNIMMAP Multiple Micronutrient Supplement formula contains 15 essential vitamins and minerals. Each tablet provides 30 mg of iron (as ferrous sulfate), 400 mcg of folic acid, and other key micronutrients, including 800 mcg of vitamin A, 70 mg of vitamin C, 200 IU of vitamin D, 10 mg of vitamin E, 1.5 mg of vitamin B1, 1.5 mg of vitamin B2, 18 mg of vitamin B3, 1.9 mg of vitamin B6, 2.6 mcg of vitamin B12, 150 mcg of iodine, 15 mg of zinc as zinc sulfate, 65 mcg of selenium, and 2 mg of copper (as copper sulfate).

Participants will be systematically randomly assigned using a computer generated sequence of numbers corresponding to the total sample size. Participants with an odd number will be assigned to the MMS group, while those with even will be assigned to the IFA group. This approach ensures impartiality and provides each participant an equal chance of being placed in either group thereby reducing bias and ensuring comparability between groups.

Criteria for discontinuation or modifying allocated intervention:
Enrolled participants who report any adverse events in either intervention arm will be referred to their doctor for guidance and to obtain permission regarding whether to continue or withdraw from the intervention. In case of any adverse event due to the intervention, the medical management will be arranged by the researcher. As per the consent, participants retain the full right to withdraw from the research study at any point, for any reason, without experiencing any negative consequences or penalties.

Intervention Type
Supplement

Primary outcome(s)
1. Height is measured using a stadiometer at baseline
2. Weight is measured using a calibrated weighing scale at baseline and during the third trimester
3. Hemoglobin level is measured using Complete Blood Count (CBC) test at baseline and during the third trimester
4. Preterm birth is measured using delivery records after birth
5. Low birth weight is measured using neonatal weight records after birth
6. Early neonatal mortality is measured using hospital records within the first 7 days after birth

Key secondary outcome(s))
1. Domestic violence experience is measured using a structured questionnaire at baseline
2. Women empowerment is measured using a structured questionnaire at baseline

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Pregnant women with gestational week less than 14 weeks
2. Low risk pregnancy and absence of any other medical and surgical complications
3. Pregnant women who are not planning to move out of the city within next 10 months
4. Not participating in any other research or nutritional program
5. Give consent to participate in this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Key exclusion criteria
1. Those with any pre-existing medical and surgical complications
2. Severe anemia (hemoglobin level < 7g/dL)
3. Those with any known mental illness

Date of first enrolment
30/11/2025

Date of final enrolment
30/03/2026

Locations

Countries of recruitment
Pakistan

Study participating centre
Sindh government Hopsital New Karachi
ST-01 sector 11-I, Behind telephone exchange, New Karachi
Karachi
Pakistan
75850

Study participating centre
Sindh Government Hospital Liaquatabad
Sharifabad Block 1 Gulberg Town
Karachi
Pakistan
75900

Sponsor information

Organisation
Baqai Medical University

ROR
https://ror.org/01v2x9m21

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The dataset analysed during the current study will be available on request from Dr Shagufta Naseer at shaguftanaseer@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes