

Multiple micronutrient supplementation improves growth and hemoglobin of infants in Gaza Strip, Palestine

Submission date 02/01/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/03/2018	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/12/2020	Condition category Nutritional, Metabolic, Endocrine	<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

Growth faltering (slower than expected rate of growth) is a common form of undernutrition in developing countries. A lack of micronutrients including vitamin A, vitamin D, iron, and zinc has been associated with undernutrition in young children, particularly growth retardation. The aim of this study is to determine the impact of micronutrient powder supplementation on the nutritional status of infants in Gaza Strip, Palestine.

Who can participate?

Infants aged 6 months

What does the study involve?

The infants are randomly allocated into two groups to receive either the National Micronutrient Supplement or both a micronutrient powder and the National Micronutrient Supplement. Weight, length, circumference of head, waist and mid-upper arm, triceps and subscapular skinfolds (for body fat determination), and blood haemoglobin are measured. Information on the infants' nutrient intakes is also obtained from their mothers.

What are the possible benefits and risks of participating?

The infants' nutritional status is expected to improve. No risks are expected from the blood samples or the supplements.

Where is the study run from?

Two healthcare clinics of the United Nations Relief and Works Agency (UNRWA) in the middle area governorate of Gaza Strip, Palestine

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

September 2015 to January 2017

Who is funding the study?

Universiti Putra Malaysia

Who is the main contact?
Ali Albelbeisi
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Multiple micronutrient supplementation improves growth and hemoglobin of infants in Gaza Strip, Palestine: a randomized community trial

Study objectives
Micronutrient supplements in powder form improves the nutritional status of Palestinian infants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Helsinki Committee for Ethical Approval, 15/09/2014, ref: PHRC/HC/27/14

Study design
Randomized community trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Nutritional status including growth parameters, biomedical measures, and dietary intakes

Interventions

Upon screening, 200 children were randomly selected (50% male and 50% female) using a table of random numbers. The random allocation procedures were employed to assign children to experimental and control groups. To avoid selection bias and reduce the chances of imbalance between groups, sealed opaque envelope method was used to assign children to groups. The infants were randomly assigned into two groups:

1. Control (National Micronutrient Supplement)
2. Experimental (micronutrient powder with National Micronutrient Supplement)

The micronutrient powder contains 15 vitamins and minerals. The National Micronutrient Supplement consists of vitamin A, vitamin D and iron. Micronutrient powder (Mix me™) was produced by DSM Nutritional Products Europe, Switzerland. The study protocol scheduled administration of micronutrient powder for 12 months as 3 sachets per week (every other day).

Weight, length, circumferences of head, waist and mid-upper arm, triceps and subscapular skinfolds, and blood hemoglobin were measured. Information on children's nutrient intakes was also obtained from the mothers.

Intervention Type

Supplement

Primary outcome(s)

1. Anthropometric measures, including body weight, length, circumferences of the head, waist, and mid-upper arm, and triceps and subscapular skinfold thickness, measured at baseline and throughout the study period (every 3 to 6 months). Z scores of these measures calculated by the WHO Anthro software, version 3.2.2, waist circumference z scores calculated based on the reference data obtained from Turkish under-six years children
2. Hemoglobin concentration: finger or heel prick blood obtained by the lab technician of the UNRWA clinic and analyzed for hemoglobin level using spectrophotometer (colorimeter) at baseline, end of the intervention, and 3 months after the end of intervention period

Key secondary outcome(s)

Calorie and nutrient intakes, including energy, carbohydrate, fat, protein, iron, vitamin A, and vitamin D, assessed using one day of 24-hour diet recall at baseline, 6 months of intervention, and at the end of the intervention period

Completion date

30/01/2017

Eligibility

Key inclusion criteria

1. Male or female infants
2. Aged 5 months + 2 weeks
3. Have normal z scores (>-2 to $<+2$ SD) of Wt/age, Lt/age and Hc/age
4. Have birth weight ≥ 2.5 to ≤ 4 kg
5. Have appropriate for gestational age (between the 10th and 90th percentile)

6. Have blood level of hemoglobin \geq 11 gram per deciliter
7. Breastfed for at least 4 months
8. Visited the UNRWA clinics for vaccination and/or routine child's growth follow up

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 months

Sex

All

Total final enrolment

200

Key exclusion criteria

1. Preterm infants (37 weeks)
2. Infants who have a history of chronic diseases (e.g. failure to thrive and metabolic or endocrine disorders)
3. Infants of diabetic mothers
4. Have a history of complications during delivery (aspiration, trauma)
5. Have a history of congenital and/or acquired neurological diagnosis (e.g., Down syndrome or cerebral palsy)

Date of first enrolment

01/10/2015

Date of final enrolment

01/01/2017

Locations**Countries of recruitment**

Palestine, State of

Study participating centre

Two health care clinics of the UNRWA

Middle Area Governorate, Gaza Strip

Palestine, State of

00972

Sponsor information

Organisation

University Putra Malaysia

ROR

<https://ror.org/02e91jd64>

Funder(s)

Funder type

University/education

Funder Name

Universiti Putra Malaysia

Alternative Name(s)

University Putra Malaysia, UPM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Malaysia

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 Ali H.A. Albelbeisi (Alialbelbeisi@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/12/2020	07/12/2020	Yes	No