ISRCTN57594793 https://doi.org/10.1186/ISRCTN57594793

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

Submission date
02/01/2018

Recruitment status
No longer recruiting

Registration date
20/03/2018

Overall study status
Completed

Last Edited
07/12/2020

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Alialbelbeisi@gmail.com

Contact information

Type(s)
Scientific

Contact name
Mr Ali Albelbeisi

Contact details
Jalan SPS5/5, Off Persiaran Serdang Perdana
43300 Seri Kembangan, Selangor
Kuala Lumpur
Malaysia
0060
+60 (0)173186913
Alialbelbeisi@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

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
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 meTM) 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 measure
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

Secondary outcome measures

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

Overall study start date
04/09/2015

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 ≥ 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

Age group
Child

Lower age limit
5 Months

Sex
Both

Target number of participants
200 (100 for each group)

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

Sponsor details
Faculty of Medicine and Health Sciences
43400 UPM Serdang, Selangor Daruh Ehsan
Kuala Lumpur
Malaysia
0060
+60 (0)389472606
chinys@upm.edu.my

Sponsor type
University/education

Website
http://www.medic.upm.edu.my/research-431

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

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

Intention to publish date
23/06/2018

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