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Supplementation with Multiple Micronutrients Intervention Trial

Submission date	Recruitment status	[_] Prospectively registered
29/03/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/03/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/06/2019	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Supplementation with Multiple Micronutrients Intervention Trial

Acronym
SUMMIT

Study objectives
Initial study:
Prenatal multivitamin supplementation, in comparison to iron/folate supplements, will reduce maternal mortality, infant mortality, and improve birth weight.

10 year follow-up study:
10-year follow-up of the Supplementation with Multiple Micronutrients Intervention Trial (Summit), the Summit Institute of Development (SID) in Mataram, Indonesia will assess the health and cognitive development of children at 8-11 years of age whose mothers had consumed multiple micronutrient supplements, as compared to iron and folic acid, during pregnancy and 3 months postpartum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Maternal and infant mortality and morbidity, and birth weight

Interventions

Initial study:
Prenatal supplementation with either iron and folate or with a multivitamin containing iron, folate, vitamins A, B1, B2, B6, B12, C, D and E, along with niacin, zinc, copper, selenium, and iodine

10 Year follow-up study:
Nearly 30,000 children will be assessed for school performance, mortality and morbidity, with approximately 3,000 of these to be evaluated for cognition, developmental status, and physiological and immune function. The scientists, including Husni Muadz (University of Mataram), Anuraj Shankar (Harvard University), Elizabeth Prado (UC Davis), Susy Sebayang, Mandri Apriatni and Ben Harefa (SID), Michael Ullman (Georgetown University), and Katie Alcock (Lancaster University), aim to document the scope and pathways whereby maternal nutrition may have long term effects on human potential, thereby providing needed evidence to inform global policy.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Miscarriage
2. Stillbirth
3. Perinatal mortality
4. Neonatal mortality
5. Early neonatal mortality
6. Late neonatal mortality
7. Infant mortality
8. Maternal mortality
9. Preterm birth
10. Birthweight
11. Low birthweight

Secondary outcome measures
Current secondary outcome measures as of 31/12/2014:
1. Child motor, cognitive, and socio-emotional development and health and morbidity at 9-12 years
2. Child anthropometry and nutritional status at 9-12 years
3. Child hemoglobin concentration at 9-12 years
4. An adapted version of the Home Observation for the Measurement of the Environment (HOME) as an indicator of the household cognitive development environment at 9-12 years
5. Maternal socio-emotional status at 9-12 years
6. Child biochemical nutritional status and biochemical markers of stress and immune function at 9-12 years
7. Child activity level, physiologic regulation and anatomical complexity at 9-12 years

Previous secondary outcome measures as of 03/03/2011:
1. Maternal Cognition and Mood
2. Child Motor, Cognitive, and Socio-Emotional Development and Health and Morbidity at age 42 months

3. Child Anthropometry and nutritional status, including dietary habits, at age 42 months
4. Child Hemoglobin concentration at age 42 months
5. An adapted version of the Home Observation for the Measurement of the Environment (HOME) as an indicator of the household cognitive development environment
6. Weight gain during pregnancy
7. Maternal biochemical nutritional status and biochemical markers of pregnancy progression

Previous secondary outcome measures:
1. Hemoglobin levels
a. At 36 weeks gestational age
b. Within 1 week of birth
c. At 12 weeks post-partum
d. Within 1 month of enrollment by 1st, 2nd, and 3rd trimester of enrollment

2. Gestational age
3. Head circumference
4. Maternal and infant morbidity
5. Cause of death
6. Maternal malaria

Overall study start date
01/07/2001

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Pregnant women and their infants.
Inclusion criteria: Confirmed pregnancy of any gestational age by physical exam or urine test and consenting to be involved in the study.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
42,000

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/2001

Date of final enrolment
30/04/2004

Locations

Countries of recruitment
Indonesia

United States of America

Study participating centre
Harvard School of Public Health
Boston
United States of America
02115

Sponsor information

Organisation
Helen Keller Int., Gov. of Indonesia, Prov. Gov. of NTB, Dis. Govs of Lombok, U of Mataram, Mataram Hospital, Johns Hopkins Univ

Sponsor details
-
Jakarta and Mataram
Indonesia
-

Sponsor type
Other

Funder(s)

Funder type
Other

Funder Name
Turner Foundation, United Nations Children's Fund (UNICEF), US Agency for International Development (USAID), Helen Keller International, Center for Health and Human Development (CHHD)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/01/2008		Yes	No
Results article	results	12/04/2008		Yes	No
Results article	results	01/06/2009		Yes	No
Results article	results	01/12/2009		Yes	No
Results article	results	01/12/2009		Yes	No
Results article	results	01/12/2009		Yes	No
Results article	results	01/03/2010		Yes	No
Results article	results	01/10/2011		Yes	No
Results article	results	01/08/2012		Yes	No
Results article	substudy results on child cognition	01/09/2012		Yes	No
Results article	substudy maternal mood and cognition results	01/10/2012		Yes	No
Results article	results	01/02/2017		Yes	No
Results article	results	01/08/2019	11/06/2019	Yes	No