

Supplementation with Multiple Micronutrients Intervention Trial

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Anuraj Shankar

Contact details
Department of Nutrition
Harvard School of Public Health
665 Huntington Ave
Boston MA
United States of America
02115
+1 617 432 4028
ashankar@hsph.harvard.edu

Additional identifiers

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

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

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

