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Maternal and Infant Nutrition Interventions in Matlab (MINIMat)

Submission date	Recruitment status	[ ] Prospectively registered
02/11/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/04/2019	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

Protocol serial number
G0501839; ICDDRB Ethical Review Committee numbers 2000-025, 2002-031, 2005-004, 2006-050

Study information

Scientific Title

Food and multiple micronutrient supplementation to pregnant women in rural Bangladesh with follow up on foetal and child growth, infant and child mortality, immune function, morbidity and cognitive development: a randomised trial with a factorial design

Acronym
MINIMat

Study objectives
Early (first trimester) invitation to daily prenatal food supplementation to undernourished women combined with multiple micronutrient supplementation improve foetal growth, infant survival and later selected functional outcomes as compared to usual (third trimester) invitation to food supplementation and standard program iron-folate supplements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ICDDRB (International Centre for Diarrhoeal Disease Research, Bangladesh) Ethical Review Committee approval received on 27/09/2000 (ref: 2000-025), 2002 (ref: 2002-031), 26/06/2005 (ref: 2005-004) and 21/12/2006 (ref: 2006-050) (protocol numbers refer to different phases in follow-up)

Study design
Randomised controlled trial with factorial design (six groups)

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nutrition-related suboptimal foetal development and growth

Interventions
A randomised factorial experiment was conducted to evaluate effects of food and mirconutrient supplements during pregnancy on health outcomes of the women and their newborn infants. There were two food groups and three micronutrient groups resulting in a total of 6 groups. The two food supplement groups were to start supplementation:
1. Immediately after diagnosis of pregnancy (early assignment), or
2. At the time of their choosing (usual care in this community)

The three types of micronutrient supplements were:
1. 30 mg iron and 400 ug of folic acid (Fe30F)
2. 60 mg of iron and 400 ug of folic acid, (Fe60F)
3. Multiple micronutrient supplement (MMS) containing 15 micronutrients as recommended by United Nations Children's Fund (UNICEF)/World Health Organization (WHO)/United Nations University (UNU): 30 mg iron, 400 µg folic acid, 800 µg RE vitamin A, 200 IU vitamin D, 10 mg vitamin E, 70 mg vitamin C, 1.4 mg vitamin B1, 1.4 mg vitamin B2, 18 mg niacin, 1.9 mg vitamin B6, 2.6 µg vitamin B12, 15 mg zinc, 2 mg copper, 65 µg selenium and 150 µg iodine.

At around 9 weeks of pregnancy women were randomly allocated to either early invitation to food supplementation (i.e. 9 weeks) or to the usual program start (at around 17 weeks). Food supplementation continued up to end of pregnancy. At 13 weeks of gestation women were randomly and double-masked allocated to the three different micronutrient supplementations that continued for the entire pregnancy.

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Iron, folic acid, multiple micronutrient supplement (MMS) (iron, folic acid, vitamin A, vitamin D, vitamin E, vitamin C, vitamin B1, vitamin B2, niacin, vitamin B6, vitamin B12, zinc, copper, selenium, iodine)

Primary outcome(s)
1. Size at birth, measured within 72 hours
2. Gestational age at birth
3. Infant mortality, prospectively assessed up to 1 year of age
4. Maternal haemoglobin and micronutrient status in third trimester, measured at 30 weeks of gestation

Key secondary outcome(s))
1. Growth, measured every month up to 1 year, thereafter every 3 months to 24 months and at 4.5 years, and cognitive development, measured at 7 months, 18 months and 4.5 years
2. Micronutrient status, measured at 6 months and 4.5 years of age
3. Immune function, measured at 4.5 years of age, and morbidity, measured monthly with 1-week recall up to 1 years, thereafter 3-monthly up to 2 years and at 4.5 years
4. Blood pressure at 4.5 years
5. Metabolic markers at 4.5 years
6. Mothers are followed with anthropometry into the next pregnancy (when applicable), measured 6 months after delivery when becoming pregnant again

Completion date
30/06/2009

Eligibility

Key inclusion criteria
Women (aged 14 - 50 years) in the study area (Matlab) with pregnancy confirmed by urine test and ultrasound with gestational age less than 14 weeks.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Chronic disease that prevented participation in the trial or planned emigration from the area.

Date of first enrolment
01/11/2001

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Bangladesh

Sweden

Study participating centre
Uppsala University
Uppsala
Sweden
75185

Sponsor information

Organisation
International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) (Bangladesh)

ROR
https://ror.org/04vsvr128

Funder(s)

Funder type
Research organisation

Funder Name

UNICEF

Alternative Name(s)
United Nations Children's Fund, United Nations Children's Emergency Fund, United Nations International Children's Emergency Fund, Fonds des Nations Unies pour l'enfance, Fondo de las Naciones Unidas para la Infancia, ,

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
United States of America

Funder Name
Styrelsen för Internationellt Utvecklingssamarbete

Alternative Name(s)
Swedish International Development Cooperation Agency, Swedish Development Cooperation, The Swedish International Development Cooperation Agency, Sida

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Sweden

Funder Name
Medical Research Council (MRC) (UK) (grant ref: G0501839)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Swedish Research Council (Sweden)

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) (Bangladesh)

Funder Name
Global Health Research Fund (Japan)

Funder Name
Child Health and Nutrition Research Initiative (CHNRI) (Bangladesh)

Funder Name
Uppsala Universitet

Alternative Name(s)
Uppsala University, UU_University, Uppsala Universitet, Sweden, UU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Funder Name
United States Agency for International Development (USAID) (USA)

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	infant development results:	01/03/2008		Yes	No
Results article	infant feeding practices results:	01/06/2008		Yes	No
Results article	household food security results:	01/07/2008		Yes	No

Results article	maternal hemoglobin, birth weight, and infant mortality results	16/05/2012		Yes	No
Results article	food insecurity results	01/06/2012		Yes	No
Results article	substudy arsenic exposure results	01/10/2012		Yes	No
Results article	child growth and body composition results	13/12/2013		Yes	No
Results article	social differentials results	07/01/2014		Yes	No
Results article	thymus development and mortality results	01/02/2014		Yes	No
Results article	cost-effectiveness results	28/05/2015		Yes	No
Results article	selenium metabolism results	01/12/2015		Yes	No
Results article	vitamin B-12, folate, ferritin and zinc results	01/12/2016		Yes	No
Results article	results	01/12/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes