

Maternal and Infant Nutrition Interventions in Matlab (MINIMat)

Submission date 02/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/02/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 01/04/2019	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.minimat.org>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G0501839; ICDDRDB 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)

ICDDRDB (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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

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

Nutrition-related suboptimal foetal development and growth

Interventions

A randomised factorial experiment was conducted to evaluate effects of food and micronutrient 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 µg of folic acid (Fe30F)
2. 60 mg of iron and 400 µg 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 measure

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

Secondary outcome measures

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 year, 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

Overall study start date

01/11/2001

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

Age group

Adult

Sex

Female

Target number of participants

5300

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)

Sponsor details

68 Shahid Tajuddin Ahmed Sharani
Mohakhali (GPO Box 128, Dhaka 1000)
Dhaka
Bangladesh
1212

Sponsor type

Research organisation

Website

<http://www.icddrb.org>

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, 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

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	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