ISRCTN08850194 https://doi.org/10.1186/ISRCTN08850194

Impact of iron/folate versus multi-micronutrient supplementation during pregnancy on birth weight: a randomised controlled trial in rural Western China

Submission date
17/11/2006

Recruitment status
No longer recruiting

Registration date
14/12/2006

Overall study status
Completed

Last Edited
19/12/2022

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

YH101-H12/03

Study information

Scientific Title
Impact of iron/folate versus multi-micronutrient supplementation during pregnancy on birth weight: a randomised controlled trial in rural Western China

Study objectives
1. The newborn infants of women receiving the multi-micronutrient supplements will at least experience a 50% reduction in prevalence of low birth weight (less than 2500 g) in comparison those receiving folate alone.
2. The newborn infants of women receiving the iron/folate supplements will at least experience a 25% reduction in the prevalence of low birth weight (less than 2500 g) in comparison those receiving folate alone
3. The women receiving the multi-micronutrient supplements in comparison those receiving iron /folate supplements, will at least experience a 30% reduction in the prevalence of anemia (Haemoglobin [Hb] less than 11 g/dL) in the third trimester (30 to 32 weeks of gestation).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee for Science and Research at the Xi'an Jiaotong University, 10/04/2002, ref: 2002002

Study design
Grouped randomised double-blind controlled 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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Low birth weight; preterm delivery; anaemia

Interventions
Hamlets were randomly assigned for women to receive one of the following three daily antenatal supplements:

1. Multi-micronutrients
2. Iron and folic acid
3. Folic acid alone (control)

The multi-micronutrient supplements were formuated to contain the Required Dietary Allowances (RDA) for each of the micronutrients and if taken throughout pregnancy should provide a sufficient intake of each micronutrient to correct any underlying deficiencies (30 mg iron, 400 µg folate, 15.0 mg zinc, 2.0 mg copper, 65.0 µg selenium, 150.0 µg iodine, 800.0 µg vitamin A, 1.4 mg Vitamin B1, 1.4 mg vitamin B2, 1.9 mg vitamin B6, 2.6 µg vitamin B12, 5.0 µg vitamin D, 70.0 mg vitamin C, 10.0 mg vitamin E, and 18.0 mg Niacin). The iron/folate supplements contained 60 mg of iron and 400 µg of folic acid. The folate-only supplement contained 400 µg of folic acid.

These supplements were identical in appearance and participants, investigators, field staff, and statisticians did nor know supplement codes until the study finished.

Intervention Type
Supplement

Primary outcome measure
1. Duration of pregnancy
2. Birth weight, length and head circumference
3. Haemoglobin level of pregnant women at the start of their third trimester

Secondary outcome measures
1. Compliance with supplements
2. Side effects of supplements
3. Complications of pregnancy:
3.1. Hypertension and preeclampsia
3.2. Antepartum haemorrhage
3.3. Infections
4. Type of delivery and type of assistance
5. Delivery complications:
5.1. Prolonged labour
5.2. Postpartum haemorrhage
5.3. Duration of maternal hospital admission
6. Early neonatal morbidity

Overall study start date
01/08/2002

Completion date
24/01/2006

Eligibility

Key inclusion criteria
Women invited to participate in the trial must be less than 28 weeks of gestation

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
7144 eligible pregnant women

Total final enrolment
5828

Key exclusion criteria
Women will be excluded from the trial if already taking iron, folate, and other micronutrients supplements for more than two weeks

Date of first enrolment
01/08/2002

Date of final enrolment
24/01/2006

Locations

Countries of recruitment
China

Study participating centre
No 76 Western Yanta Road
Xi'an
China
710061

Sponsor information

Organisation
United Nations Children's Fund (UNICEF) (China)

Sponsor details
c/o Lilian Selenje
Health and Nutrition
12 Sanlitun Lu

Beijing
China
100600

Sponsor type
Research organisation

Website
http://www.unicef.org/china/index.html

ROR
https://ror.org/02dg0pv02

Funder(s)

Funder type
Research organisation

Funder Name
UNICEF (Project No.: YH101-H12/03)

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	07/11/2008		Yes	No
Results article	results	09/07/2009		Yes	No
Results article	30-month follow-up results	01/02/2012		Yes	No
Results article	results	01/08/2015		Yes	No
Results article	results	01/11/2016		Yes	No
Results article	results	01/09/2018		Yes	No
Results article	results	01/06/2020	12/08/2019	Yes	No
Results article	14-year follow-up	07/12/2022	19/12/2022	Yes	No