

The effects of antenatal multiple micronutrient supplementation on birth weight, gestation and infection: a double blind, randomised controlled trial conducted in Nepal

Submission date 17/06/2004	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 21/09/2004	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/10/2022	Condition category Neonatal Diseases	☐ 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

Protocol serial number

060394; 99-CH-16

Study information

Scientific Title

The effects of antenatal multiple micronutrient supplementation on birth weight, gestation and infection: a double blind, randomised controlled trial conducted in Nepal

Acronym

MIRA (Mother and Infant Research Activities) - a Nepali Non-Governmental Organisation (NGO):
Janakpur Multiple Micronutrient Supplementation Study

Study objectives

Neonatal mortality is the biggest contributor to global mortality of children younger than five years, and low birth weight is a crucial underlying factor. This study is a double blind, randomised controlled trial of the effects of antenatal multiple micronutrient supplementation on birth weight, gestation and perinatal infection, conducted in Dhanusha district, Nepal.

Added 15/02/2007:

1. Second and third trimester supplementation with a multiple micronutrient regime will increase birth weight
2. Second and third trimester supplementation with a multiple micronutrient regime will prolong gestation
3. Second and third trimester supplementation with a multiple micronutrient regime will make mothers less susceptible to infection

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Double-blind randomised controlled trial

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Low birth weight

Interventions

Intervention arm (600 participants):

Daily multiple micronutrient tablet from enrolment to delivery: Vitamin A 800 mcg, Vitamin E 10 mg, Vitamin D 5 mcg, Vitamin B1 1.4 mg, Vitamin B2 1.4 mg, Niacin 18 mg, Vitamin B6 1.9 mg, Vitamin B12 2.6 mcg, Folic acid 400 mcg, Vitamin C 70 mg, Iron 30 mg, Zinc 15 mg, Copper 2 mg, Selenium 65 mcg, Iodine 150 mcg.

Control arm (600 participants):

Daily government-recommended supplement from enrolment to delivery: Iron 60 mg, Folic acid 400 mcg.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Supplements, vitamins

Primary outcome(s)

Added 15/02/2007:

Primary outcomes (1200 participants):

1. Birth weight, length and head circumference measured within 72 hours of birth
2. Gestation at birth calculated on the basis of obstetric ultrasound biometry at enrolment

Key secondary outcome(s)

Added 15/02/2007:

1. Micronutritional Outcomes (200 participants): venous blood collected at 32 weeks gestation for measurement of plasma vitamins A, C, E and ferritin
2. Immunological outcomes (600 participants):
 - 2.1. Clinical indicators of infection at every contact
 - 2.2. Venous blood collected at 32 weeks gestation for measurement of neopterin
 - 2.3. Breast milk collected at one month postpartum for measurement of sodium/potassium ratio

Completion date

01/07/2004

Eligibility

Key inclusion criteria

1. Pregnant women attending for antenatal care at Janakpur Zonal Hospital, Dhanusha District, Nepal

As of 15th February 2007 the following details were added to this trial record:

2. Enrolment at up to 20 weeks zero days gestation
3. Singleton pregnancy
4. No major foetal anomaly detected on obstetric ultrasound at enrolment
5. No pre-existing maternal illness that would be expected to affect foetal growth

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

1200

Key exclusion criteria

Added 15/02/2007:

1. Pregnancy at gestations greater than 20 weeks zero days
2. Pre-existing maternal illness of a nature likely to affect pregnancy
3. Multiple pregnancy detected by obstetric ultrasound at enrolment
4. Residence potentially inaccessible for home follow-up

Date of first enrolment

11/08/2002

Date of final enrolment

22/10/2003

Locations**Countries of recruitment**

United Kingdom

England

Nepal

Study participating centre

Institute of Child Health

London

United Kingdom

WC1N 1EH

Sponsor information**Organisation**

Institute of Child Health (UK)

ROR

<https://ror.org/02jx3x895>

Funder(s)**Funder type**

Charity

Funder Name

Wellcome Trust

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

Results and Publications

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	Birth weight and duration of gestation	01/03/2005		Yes	No
Other publications	Weight and size of children aged 2 years	09/02/2008		Yes	No
Other publications	Blood pressure, weight and size of children aged 8 years	01/11/2014		Yes	No
Other publications	Cognitive function at 12 years	28/02/2018	27/10/2022	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes