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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

Registration date
21/09/2004

Overall study status
Completed

Last Edited
27/10/2022

Condition category
Neonatal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.mira.org.np/research.htm

Contact information

Type(s)
Scientific

Contact name
Prof Anthony Costello

Contact details
30 Guilford Street
London
United Kingdom
WC1N 1EH
+44 (0)20 7905 2261
anthony.costello@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Double-blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
11/08/2002

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

Age group
Adult

Sex
Female

Target number of participants
1200

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
England

Nepal

United Kingdom

Study participating centre
Institute of Child Health
London

United Kingdom
WC1N 1EH

Sponsor information

Organisation
Institute of Child Health (UK)

Sponsor details
30 Guilford Street
London
United Kingdom
WC1N 1EH

Sponsor type
Research organisation

Website
http://www.ich.ucl.ac.uk/ich/

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

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	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