

Prenatal iron supplementation versus iron supplementation plus deworming in reducing low birthweight in hookworm-endemic areas

Submission date
09/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
09/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
03/03/2009

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Reducing low birthweight in hookworm-endemic areas: a randomised controlled trial (RCT) of prenatal iron versus iron plus mebendazole

Study objectives

To determine the effectiveness of mebendazole plus iron supplements versus placebo plus iron supplements on infant birthweight and maternal anaemia, in pregnant women living in a hookworm-endemic area.

Please note that as of 03/03/2009 the anticipated start and end dates in this record were amended. The previous dates are as follows:

Initial anticipated start date: 01/01/2005

Initial anticipated end date: 31/12/2005

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. MUHC-Montreal General Hospital Research Ethics Committee approved on the 8th March 2004
2. The Comité Institucional de Ética de la Universidad Peruana Cayetano Heredia (Peru)
3. The Comité Ética de la Dirección General de Salud de las Personas del Ministerio de Salud de Peru (Peru)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Anaemia, hookworm infection

Interventions

One dose of mebendazole (500 mg) or placebo similar to the mebendazole. Daily iron supplements (60 mg iron) to both groups.

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Mebendazole, iron supplementation

Primary outcome measure

Mean infant birth weight

Secondary outcome measures

Change in maternal haemoglobin between baseline and delivery

Overall study start date

01/04/2003

Completion date

01/06/2004

Eligibility**Key inclusion criteria**

1. Second trimester pregnant women aged 18 to 44 years old
2. Not having received anthelmintic treatment for six months prior to randomisation
3. Consents to participate

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

1042

Key exclusion criteria

1. Women with severe anaemia (haemoglobin levels less than 80 g/l)
2. Women who have medical conditions for which follow-up is required

Date of first enrolment

01/04/2003

Date of final enrolment

01/06/2004

Locations

Countries of recruitment

Canada

Peru

Study participating centre

Division of Clinical Epidemiology

Montreal

Canada

H3A 1A4

Sponsor information

Organisation

Montreal General Hospital (Canada)

Sponsor details

1650 Cedar Ave

Montreal

Canada

H3G 1A4

Sponsor type

Hospital/treatment centre

Website

<http://www.muhc.ca/>

ROR

<https://ror.org/04gbhgc79>

Funder(s)

Funder type

Research organisation

Funder Name

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	results	01/10/2005		Yes	No
Results article	results	01/10/2006		Yes	No