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

Submission date	Recruitment status	[_] Prospectively registered
09/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/03/2009	Infections and Infestations	

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

MCT-53575

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 Comite Institucional de Etica de la Universidad Peruana Cayetano Heredia (Peru)
3. The Comite Etica de la Direccion 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