

The effect of worm infections during pregnancy on immunisations and infections in infants

Submission date 22/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/08/2020	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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
064693

Study information

Scientific Title
The impact of helminths on the response to immunisation and on the incidence of infection and disease in childhood in Uganda

Study objectives

That helminth infection in pregnancy and in early childhood affects the immune response to childhood vaccines and susceptibility to disease in childhood.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Science and Ethics Committee of the Uganda Virus Research Institute in 2001
2. Uganda National Council for Science and Technology in 2001
3. London School of Hygiene & Tropical Medicine in 2001, ref: 790

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Helminthiasis

Interventions

1. Randomised, double-blind, placebo controlled trial of albendazole versus placebo and praziquantel versus placebo during pregnancy (all mothers treated with both six weeks after delivery)
2. Randomised, double blind placebo controlled trial of three-monthly albendazole versus placebo from age 15 months (all infants treated annually for helminths identified on analysis of a stool sample)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Albendazole, praziquantel

Primary outcome(s)

Current primary outcome measure(s):

1. Immune responses in infants:
 - 1.1. To selected childhood vaccines
 - 1.2. To selected infectious diseases
 - 1.3. To selected helminths
2. Incidence of childhood diseases
3. Primary outcomes at age nine years
 - 3.1. Reported wheeze in last 12 months
 - 3.2. SPT positivity to any allergen
 - 3.3. Allergen-specific IgE to any allergen

Previous primary outcome measure(s):

1. Immune responses in infants:
 - 1.1. To selected childhood vaccines
 - 1.2. To selected infectious diseases
 - 1.3. To selected helminths
2. Incidence of childhood diseases

Key secondary outcome(s)

Current secondary outcome measure(s):

1. Measures of:
 - 1.1. Anaemia
 - 1.2. Growth
 - 1.3. Development
2. Incidence of allergic disease events
3. Secondary outcomes at age nine years
 - 3.1. Reported eczema in last 12 months
 - 3.2. Visible flexural eczema
 - 3.3. Forced expiratory volume in one second (FEV1)

Previous secondary outcome measure(s):

1. Measures of:
 - 1.1. Anaemia
 - 1.2. Growth
 - 1.3. Development
2. Incidence of allergic disease events

Completion date

30/04/2011

Eligibility

Key inclusion criteria

1. Pregnant women (aged 14 to 47 years) in the second or third trimester
2. Resident in the study area
3. Planning to deliver at Entebbe Hospital
4. Willing to know Human Immunodeficiency Virus (HIV) status

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Anaemia (more than or equal to 8 g/dl), bloody diarrhoea
2. Clinical evidence of severe liver disease
3. History of adverse reaction to anthelmintics
4. Already enrolled in previous pregnancy
5. Abnormal pregnancy (e.g. bleeding)

Date of first enrolment

01/04/2003

Date of final enrolment

30/04/2011

Locations

Countries of recruitment

Uganda

Study participating centre

Uganda Virus Research Institute

Entebbe

Uganda

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Sponsor information

Organisation

London School of Hygiene and Tropical Medicine (UK)

ROR

<https://ror.org/00a0jsq62>

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust (grant refs: 079110 and 095778)

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

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	21/12/2005		Yes	No
Results article	results	01/09/2007		Yes	No
Results article	results	18/03/2009		Yes	No
Results article	results	15/02/2010		Yes	No
Results article	results	01/01/2011		Yes	No
Results article	results	01/05/2011		Yes	No
Results article	results	02/09/2011		Yes	No
Results article	results	01/10/2011		Yes	No
Results article	results	01/07/2012		Yes	No
Results article	results	01/07/2012		Yes	No
Results article	results	01/07/2013		Yes	No
Results article	results	06/08/2014		Yes	No
Results article	results	08/02/2017		Yes	No
Results article	results	17/05/2019	06/08/2020	Yes	No
Other publications	design review	01/09/2007		Yes	No