ISRCTN32849447 https://doi.org/10.1186/ISRCTN32849447

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

Submission date	Recruitment status	[_] Prospectively registered
22/07/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/09/2026	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

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

Primary study design
Interventional

Study design
Randomised controlled trial

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

Total final enrolment

0

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 anthelminthics
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
Results article	Cohort profile of the parent study EMaBS	26/08/2026	02/09/2026	Yes	No

Other publications	design review	01/09/2007		Yes	No
Protocol (other)	new round of data collection nested within the Entebbe Mother and Baby Study (EMaBS)	07/04/2026	08/04/2026	No	No