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Impact of maternal and infant geohelminth infections on atopy and vaccine immunity in infants living in rural tropical region of Ecuador [Impacto de las infecciones con geohelmintos en madres embarazadas e infantes sobre atopia e inmunidad a vacunas en infantes que viven en zonas rurales tropicales del Ecuador]

Submission date 30/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/05/2010	**Overall study status** Completed	
Last Edited 27/10/2021	**Condition category** Other	

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
074679

Study information

Scientific Title
Impact of maternal and infant geohelminth infections on atopy and vaccine immunity in infants living in rural tropical region of Ecuador: a prospective birth cohort following up newborns to 5 years of age

Acronym
ECUAVIDA

Study objectives
Exposure to maternal geohelminth infections and infant geohelminth infections within the first 2 years of life:
1. Suppresses immune responses to childhood vaccines
2. Suppresses aeroallergen skin test reactivity
3. Protects against the development of eczema and asthma

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Hospital Pedro Vicente Maldonado, Pichincha Province, Ecuador, 13/06 /2005

Study design
Observational; prospective birth cohort study

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Vaccine immunity, allergic sensitisation, eczema, asthma

Interventions
The primary exposures are maternal geohelminth infections and infant infections during the first 2 years of life. Stool samples are collected during pregnancy or at the time of birth to determine maternal infection status and at 3, 7, 13, 18, and 24 months to determine infant infection status. Stool samples are examined using a combination of methods including modified Kato-Katz method, formol-ether concentration, and carbon-coproculture. Observations for measurement of differences are made at 7, 13, 24, 36, and 60 months of age. Follow-up of all participants will be to 5 years of age.

Intervention Type
Biological/Vaccine

Phase
Not Applicable

Primary outcome(s)
1. Vaccine immunity: protective levels of antibodies to rotavirus, Hemophilus influenzae type B, hepatitis B virus, OPV serotype 3, and tetanus toxoid
2. Allergic sensitization: allergen skin test reactivity to at least one aeroallergen tested
3. Eczema: at least one presentation with eczema by 3 years of age
4. Asthma: Asthma diagnosed at 5 years of age

Key secondary outcome(s))
Studies of intermediate immunological mechanisms that mediate exposure-outcome effects including:
1. Immune homeostasis: measured by spontaneous IL-10 in whole blood
2. Immune regulation/suppression - IL-10 to tetanus toxoid (TT), tuberculin (PPD), Ascaris lumbricoides or Dermatophagoides pteronyssinus
3. Th2 polarization - ratio of IL-5 to IFN-g TT, PPD or Staphylococcus enterotoxin B
4. Pro-inflammatory responses - IL-8 to endotoxin

These responses will be measured at 2, 3, or 5 years depending on the relevant exposure-outcome association.

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Neonate born within the previous 14 days
2. Gestational age of at least 34 weeks
3. At least one stool sample collected during third trimester of pregnancy
4. The mother lives within the geographic limits of the District of Quininde, Esmeraldas Province
5. The mother plans to live within the District of Quininde, Esmeraldas Province for at least 3 years
6. The mother's household is accessible

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria

1. Neonate of greater than 14 days age
2. Gestational age less than 34 weeks
3. No stool sample collected during third trimester of pregnancy
4. The mother does not live within the geographic limits of the District of Quininde, Esmeraldas Province
5. The mother does not plan to live within the District of Quininde, Esmeraldas Province for at least 3 years
6. The mother's household is not easily accessible

Date of first enrolment
01/12/2005

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
Ecuador

Study participating centre
Universidad san Francisco de Quito
Quito
Ecuador
N/A

Sponsor information

Organisation
Ecuadorian Foundation for Health Research (Fundacion Ecuatoriana Para Investigacion en Salud) (Ecuador)

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (grant ref: 074679)

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
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	results	15/06/2016		Yes	No
Results article		01/03/2021	22/03/2021	Yes	No
Results article	childhood wheeze cross-sectional analysis	30/11/2020	27/10/2021	Yes	No
Protocol article	protocol	29/06/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes