

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 geohelminthos 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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/10/2021	Condition category Other	<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

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 Quinde, Esmeraldas Province
5. The mother plans to live within the District of Quinde, 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