

ZEN



Zika en Embarazadas y Niños en Colombia

Appendix I3: ZEN Study Overview for Infant Follow-up to 6 Months of Age



Colombia's Instituto Nacional de Salud (INS) and the US Centers for Disease Control and Prevention (CDC) are conducting a study to evaluate the association between Zika virus infection and adverse maternal, fetal, and infant health outcomes. The study will enroll women in the first trimester (first 3 months) of pregnancy, their male partners, and their infants.

What are the goals of ZEN?

1. Identify and describe factors that increase the risk of Zika virus infection during pregnancy
2. Determine in what weeks of the pregnancy Zika virus is harmful to the fetus
3. Determine how long Zika virus stays in bodily fluids, including blood, urine, and semen
4. Identify factors that increase the risk of Zika virus transmission from the pregnant woman to her fetus during pregnancy and from mother to baby just after childbirth

Who will participate in ZEN?

- Pregnant women 16 years of age or older who are in their first trimester (first 3 months) of pregnancy
- Male partners (18 years or older) of women enrolled in ZEN
- Infants born to women enrolled in ZEN

How will information be collected by ZEN?

Information will be collected at clinic visits at participating clinics. Study staff will collect information through

- Questionnaires
- Biological samples (blood, urine, and semen)
- Review of medical records

Where will ZEN take place?

- The study will take place at participating clinics in Colombia's private and public healthcare systems in Barranquilla, Soledad, Bucaramanga, Girón, Tuluá, Buga, Palmira, and several other sites to be determined.



The ZEN study will

- Provide critical information leading to evidence-based strategies to prevent Zika virus infection in pregnancy
- Improve counseling of patients about risks to themselves, their pregnancies, and their children
- Increase the preparedness of agencies providing services to affected children and families



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Pregnant Women Participants

Women 16 years of age and older will be recruited in the first trimester of pregnancy at participating clinics in Colombia's private and public healthcare systems. Participants will be followed through their pregnancy, delivery, and up to 6 months after birth. Information will be gathered from participants' medical records about tests performed during pregnancy or during the immediate postpartum period. Additional Zika virus tests that may be conducted as part of the study (e.g., serial testing for Zika virus during pregnancy) will be paid for using study funds.

Pregnant women will do the following as part of ZEN:

- Provide a blood sample at the time of enrollment, at prenatal appointments, and at delivery, or if she develops symptoms of Zika virus infection.
- Provide monthly urine samples until the 32nd week of pregnancy.
- Complete questionnaires at every visit.
- If Zika virus is confirmed (detected through urine or blood), provide a bi-weekly blood sample until two consecutive negative Zika virus test results are received.

Male Partner Participants

Male partners will be recruited through the participating pregnant women who are enrolled in the study.

Male partners will do the following as part of ZEN:

- Provide blood samples at enrollment and if symptoms of Zika virus infection develop.
- Provide monthly urine samples through the second trimester of their partner's pregnancy or until the partner's pregnancy ends if prior to the end of the second trimester.
- Complete questionnaires at every visit.
- If Zika virus infection is confirmed (detected through urine or blood), provide a bi-weekly semen sample until two consecutive negative Zika virus test results are received or until the end of the partner's pregnancy.

Infant Participants

Newborns of mothers participating in the study will be included in the study from birth to 6 months of age. Any infant health conditions or results of medical testing conducted as part of routine clinical care during this 6-month period will be gathered from participants' medical records.

Infants will do the following as a part of ZEN:

- Head circumference will be measured every two weeks.
- Blood samples taken at birth to identify infection acquired before birth or if the infant develops symptoms of Zika virus infection postnatally.
- Cranial ultrasound may be performed up to 6 months of age.
- Hearing will be examined at 1, 3, and 6 months of age.
- Eye exam will be performed at approximately 1 month and 6 months of age.
- Developmental screens at 2, 3 and 6 months of age.
- Bi-weekly urine samples will be collected to detect Zika virus.
- Questionnaires will be completed by the mother or guardian at every visit through 6 months of age.