

Record 1 of 1



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Completed ⓘ

A Phase 1, First-in-human, Double-blinded, Randomized, Placebo-controlled Trial of a Zika Virus Purified Inactivated Vaccine (ZPIV) With Alum Adjuvant in Healthy Flavivirus-naive and Flavivirus-Primed Subjects.

ClinicalTrials.gov ID ⓘ NCT02963909

Sponsor ⓘ National Institute of Allergy and Infectious Diseases (NIAID)

Information provided by ⓘ National Institute of Allergy and Infectious Diseases (NIAID) (Responsible Party)

Last Update Posted ⓘ 2024-04-22

Study Details Tab

Study Overview

Brief Summary

Phase 1 study to evaluate two doses of Alum Adjuvanted Zika Virus Purified Inactivated Vaccine (ZPIV) administered 28 days apart. The study will enroll 75 flavivirus naïve healthy adult subjects into 3 equal groups sequentially. Each group will include 20 ZPIV recipients and 5 placebo recipients. Group 1 will receive two ZPIV or placebo doses 28 days apart. Those in Group 1 who consent to a third ZPIV dose will receive 5.0 mcg dose of ZPIV or placebo administered IM on Day 224. Group 2 subjects will receive a two-dose regimen of IXIARO® 28 days apart; two ZPIV or placebo doses three months later 28 days apart. Those in Group 2 who consent to a third ZPIV dose will receive it on Day 336. Group 3 subjects will receive one dose of YF-VAX® followed three months later by two ZPIV or placebo doses 28 days apart. Those in Group 3 who consent to a third ZPIV dose will receive it on Day 308. In each group,

Feedback

those who do not agree to receive the third ZPIV dose will be followed based on the schedule. The primary objectives are: 1) To evaluate the safety and reactogenicity of a two-dose homologous prime boost regimen of ZPIV among flavivirus-naïve, YF-VAX® primed, and IXIARO® primed subjects; 2) To evaluate the safety and reactogenicity of a third dose of ZPIV in consenting subjects.

Detailed Description

This study is a single-center, double-blinded, placebo-controlled, first-in-human, Phase 1 study to evaluate the safety, reactogenicity, and immunogenicity of two doses of alum adjuvanted Zika Virus Purified Inactivated Vaccine (ZPIV) administered 28 days apart. The study will enroll 75 flavivirus naïve healthy male and non-pregnant, non-breastfeeding female adult subjects (ages 18-49, inclusive) into 3 equal groups sequentially, starting with Group 1 followed by Group 2 and then Group 3. Screening will occur within 40 days of first vaccination. Each group will include 20 ZPIV recipients and 5 placebo recipients. Two sentinel subjects from Group 1 will be enrolled first and will receive ZPIV in an open-label fashion first. The next 23 subjects (18 ZPIV, 5 placebo) will be randomized into Group 1. This will be followed by the randomization of 25 subjects into Group 2 (JE priming). The remaining 25 subjects to enroll will be randomized into Group 3 (YF priming). Group 1 subjects will receive two 5.0 mcg doses of ZPIV or placebo administered IM on Days 1 and 29. Those in Group 1 who consent to a third ZPIV dose will receive 5.0 mcg dose of ZPIV or placebo administered IM on Day 224. Group 2 subjects will receive a two-dose regimen of IXIARO® (Valneva) 28 days apart; two ZPIV or placebo doses will be administered three months later IM 28 days apart. Those in Group 2 who consent to a third ZPIV dose will receive it on Day 336. Group 3 subjects will receive one dose of YF-VAX® (Sanofi Pasteur) followed three months later by two ZPIV or placebo doses administered IM 28 days apart. Those in Group 3 who consent to a third ZPIV dose will receive it on Day 308. In each group, those who do not agree to receive the third ZPIV dose will be followed based on the schedule. The primary objectives are: 1) To evaluate the safety and reactogenicity of a two-dose homologous prime boost regimen of ZPIV among flavivirus-naïve, YF-VAX® primed, and IXIARO® primed subjects; 2) To evaluate the safety and reactogenicity of a third dose of ZPIV in consenting subjects. The secondary objectives are: 1) To evaluate the quantitative humoral immune response at 28 days after the first and second ZPIV administration, and 112, 196, 280, and 364 days after the first ZPIV administration for each of the three groups in subjects who consent to two doses of ZPIV; 2) To evaluate the quantitative humoral immune response at 28 days after the first and second ZPIV administration, and 112, 196, 224 days after the first ZPIV administration and at 28, 84, and 168 days after the third ZPIV administration for Group 1 subjects who consent to third dose; 3) To evaluate the quantitative humoral immune response at 28 days after the first and second ZPIV administration, and 112, 224 days after the first ZPIV administration and at 28, 84, and 168 days after the third ZPIV administration for Group 2 and 3 subjects who consent to third dose.

Official Title

A Phase 1, First-in-Human, Double-blinded, Randomized, Placebo-controlled Trial to Evaluate the Safety, Reactogenicity, and Immunogenicity of an Alum Adjuvanted Zika Virus Purified Inactivated Vaccine (ZPIV) in Healthy Flavivirus-Naïve and Flavivirus-Primed Subjects

Conditions ⓘ

Zika Virus Infection

Intervention / Treatment ⓘ

- Biological: IXIARO
- Other: Placebo
- Biological: YF Vax 17D Strain
- Biological: Zika Virus Purified Inactivated Vaccine (ZPIV)

Other Study ID Numbers ⓘ

- 16-0062

Study Start (Actual) ⓘ

2016-11-01

Primary Completion (Actual) ⓘ

2018-10-30

Study Completion (Actual) ⓘ

2018-10-30

Enrollment (Actual) ⓘ

75

Study Type ⓘ

Interventional

Phase ⓘ

Phase 1

Resource links provided by the National Library of Medicine

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>) related topics: [Vaccines](https://medlineplus.gov/vaccines.html) (<https://medlineplus.gov/vaccines.html>), [Viral Infections](https://medlineplus.gov/viralinfections.html) (<https://medlineplus.gov/viralinfections.html>), [Zika Virus](https://medlineplus.gov/zikavirus.html) (<https://medlineplus.gov/zikavirus.html>).

[Genetic and Rare Diseases Information Center](https://rarediseases.info.nih.gov/gard) (<https://rarediseases.info.nih.gov/gard>) resources:
[Zika Virus Infection](https://rarediseases.info.nih.gov/diseases/12894/zika-virus-infection) (<https://rarediseases.info.nih.gov/diseases/12894/zika-virus-infection>).

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>).

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (<https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>).

This study has 1 location

United States

Maryland Locations

 **Silver Spring, Maryland, United States, 20910-7500**

Walter Reed Army Institute of Research -
Clinical Trials Center

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](https://clinicaltrials.gov/study-basics/learn-about-studies) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

1. Must be a male or non-pregnant, non-breastfeeding female between the ages of 18 and 49 years, inclusive, at the time of screening and enrollment.
2. Must be willing and able to read, sign, and date the informed consent document before study-related procedures are performed.
3. Must be willing and able to comply with study requirements and be available for follow-up visits for the entire study.
4. Must have a means to be contacted by telephone.
5. Must have a body mass index (BMI) ≥ 18.1 and < 35.0 kg/m².
6. Must have acceptable screening laboratory findings within 40 days before day 1.

- Acceptable clinical laboratory parameters include no more than Grade 1 on toxicity scale.
- White Blood Cell (WBC), Hemoglobin, and platelet count will be reported as part of the Complete Blood Count (CBC). These labs will be graded according to the toxicity scale. Other results included on the CBC panel will not be graded. They will be reviewed by an investigator who will determine clinical significance and may be used to determine additional workup.
- Sodium, potassium, blood urea nitrogen (BUN), creatinine, random glucose, total protein, albumin, calcium, AST, ALT, total bilirubin, and alkaline phosphatase will be reported as part of the Complete Metabolic Panel (CMP). These labs will be graded according to the toxicity scale. Other results included on the CMP panel will not be graded. They will be reviewed by an investigator who will determine clinical significance and may be used to determine additional workup.

Note: If laboratory screening tests are out of acceptable range, repeat of screening tests is permitted one time, provided there is an alternative explanation for the out of range value.

7. Must be in good health based on the investigator's clinical judgment when considering findings from past medical history, medication use, vital signs, and an abbreviated physical examination.

Note 1: Good health is defined by the absence of any medical condition described in the exclusion criteria in a subject with a normal abbreviated physical exam and vital signs. If the subject has a preexisting condition not listed in the exclusion criteria, the condition cannot meet any of the following criteria: first diagnosed in the last 3 months; worsening in terms of clinical outcome in the last 6 months; or involves need for medication that may pose a risk to the subject's safety or impede assessment of AEs or immunogenicity if they participate in the study.

Note 2: An abbreviated physical exam differs from a complete exam in that it does not include a genitourinary and rectal exam.

Note 3: Vital signs must be normal by protocol toxicity grading scale or determined to be normal-variant by investigator. In the event of an abnormal heart rate or blood pressure due to physiological variation or activity, the subject may rest for 10 minutes in a quiet room, and then blood pressure and/or heart rate may be re-measured. Repeated vital signs may be used to determine eligibility.

8. Women of childbearing potential must have a negative urine pregnancy test at screening and a negative urine pregnancy test immediately prior to each vaccination.

Note: All female subjects are considered of childbearing potential unless postmenopausal or surgically sterile and ≥ 3 months have passed since sterilization procedure.

Postmenopausal is defined as amenorrhea for ≥ 12 months without an alternative medical cause. Permanent female sterilization procedures include tubal ligation, bilateral salpingectomy, hysterectomy, bilateral oophorectomy, or successful Essure placement.

9. Women of childbearing potential must use an acceptable method of contraception from one month (30 days) prior to the first vaccination until at least 60 days after the last vaccination.
- Acceptable methods of contraception include the following: Use highly effective contraceptive methods, defined by $<1\%$ failure rate per year independent of user adherence, including long-acting reversible contraception (LARC): progestin-releasing subdermal implants and intrauterine devices (IUD). Use effective contraceptive methods, defined by 5-9% failure rate with typical use and $<1\%$ failure rate with consistent and correct use, including: prescription oral contraceptives, contraceptive injections, combined pill, progestin-only pill, hormone-releasing transdermal patch or vaginal ring, and depot medroxyprogesterone acetate injection (Depo-Provera). Have one male sex partner who has had a vasectomy ≥ 3 months prior. Male partner with barrier protection plus the use of vaginal spermicide. Practice abstinence defined as refraining from heterosexual intercourse from 30 days before first vaccination until at least 60 days after last ZPIV vaccination.
10. Female subjects must agree to not donate eggs (ova, oocytes) from the start of screening period until at least 60 days after receiving the last ZPIV vaccination.

Exclusion Criteria:

1. Has plans to become pregnant, or is currently pregnant or breastfeeding.
2. Has plans to travel to an area with active ZIKV, DENV, YFV, or JEV transmission during the study or returned from an endemic area with these diseases within 30 days of screening.

NOTE: Refer to Centers for Disease Control and Prevention (CDC) website for areas with active ZIKV transmission: <http://www.cdc.gov/zika/geo>

3. Has history of vaccination with a licensed or investigational flavivirus vaccine or reportedly diagnosed with a flavivirus infection or disease. Includes subject's verbal history of vaccination or disease with any of the following flaviviruses:
 - YFV: YF-VAX®, Stamaril, or Bio-Manguinhos YF vaccine;
 - JEV: investigational vaccine or licensed vaccine (IXIARO®);

- DENV: investigational vaccine or Sanofi Pasteur newly licensed vaccine;
 - WNV: investigational vaccine;
 - ZIKV;
 - Other: St. Louis encephalitis, or TBEV.
4. Plans to receive a licensed flavivirus vaccine or participate in another flavivirus vaccine trial during the study.
5. Seropositive to DENV, ZIKV, YFV, JEV, or WNV by microneutralization (MN) titer assay.
- Positive results may be repeated if technical error is suspected. Additional testing to confirm Zika exposure and any required reporting or counseling will be referred to the appropriate medical clinic.
6. Confirmed positive for active infection of human immunodeficiency virus (HIV), hepatitis C virus (HCV), or presence of Hepatitis B surface antigen.
7. Has known or suspected congenital or acquired immunodeficiency, or recent history or current use of immunosuppressive therapy.
- Anti-cancer chemotherapy or radiation therapy within the preceding 6 months, or long-term (at least 2 weeks within the previous 3 months) systemic corticosteroids therapy (at a dose of at least 0.5 mg/kg/day). Intranasal or topical prednisone (or equivalent) is allowed. Includes medication which, in the opinion of the investigators(s), will impact the subject's immune response.
8. History of organ and/or stem cell transplantation.
9. Has history of malignancy other than squamous cell or basal cell skin cancer, unless there has been surgical excision that is considered to have achieved a cure.
- Subjects with a history of skin cancer must not be vaccinated at the previous tumor site.
10. Has history of chronic or acute severe neurologic condition.
- Including: Neurologic and Neuroinflammatory Disorders: ADEM, including site specific variants, Cranial Nerve Disorders (including paralyses/paresis), GBS (including Miller Fisher Syndrome and other variants), Immune-mediated Peripheral Neuropathies and Plexopathies, Optic Neuritis, Multiple Sclerosis, Narcolepsy, Transverse Myelitis, meningitis, or meningoencephalitis.
11. Has diabetes mellitus type 1 or type 2, including cases controlled with diet alone.
- Note: history of isolated gestational diabetes is not an exclusion criterion.
12. Has history of thyroidectomy or thyroid disease requiring medication during the last 12 months.
13. Has major psychiatric illness during the last 12 months that in the investigator's opinion would preclude participation.
14. Has history of other chronic disease or condition including:
- autoimmune disease, hypercholesterolemia, chronic hepatitis or cirrhosis, chronic pulmonary disease, chronic renal disease, and chronic cardiac disease including hypertension even if medically controlled.
 - Includes the conditions and diagnoses defined as AESI in Section 9.

- Vital signs must be normal by protocol toxicity grading scale or determined to be normal-variant by investigator. In the event of an abnormal heart rate or blood pressure due to physiological variation or activity, the subject may rest for 10 minutes in a quiet room, and then blood pressure and/or heart rate may be re-measured. Repeated vital signs may be used to determine eligibility.
15. Has current or past history of substance abuse that in the investigator's opinion would preclude participation.
 16. Has tattoos, scars, or other marks on both deltoid areas that would, in the opinion of the investigator, interfere with assessment of the vaccination site.
 17. Has a history of chronic urticaria (recurrent hives).
 18. Has known allergy or history of anaphylaxis, or other serious reaction to a vaccine or vaccine component. - Note: includes protamine sulfate, eggs or egg products, chicken protein, gelatin, sorbitol, aminoglycosides (e.g., neomycin and streptomycin), or any of the constituents of the study vaccines including alum.
 19. Had major surgery (per the investigator's judgment) in the month prior to screening or plans to have major surgery during the study.
 20. Received blood products or immunoglobulin in the 3 months prior to screening or plans to use during the course of the study.
 21. Donated a unit of blood within 8 weeks before Day 1 or plans to donate blood during the course of the study.
 22. Received live attenuated vaccine from 30 days before Day 1 until 30 days after the last vaccination.
 23. Received killed or inactivated vaccine from 14 days before Day 1 and until 14 days after the last vaccination.

- Note: Subjects may receive inactivated seasonal influenza vaccine 14 days prior or 30 days after each study vaccination (JEV, YFV, or ZPIV).
 24. Severe allergy or anaphylaxis to latex.
 25. Received experimental therapeutic agents within 3 months prior to the first study vaccination or plans to receive any experimental therapeutic agents during the course of the study.
 26. History of thymus disorder including myasthenia gravis, thymoma, or prior thymectomy.
 27. Is currently participating or plans to participate in another clinical study that involves:
 - An investigational product, blood drawing, or an invasive procedure requiring administration of anesthetics or intravenous (IV) dyes or removal of tissue. This includes endoscopy, bronchoscopy, or administration of IV contrast.
 28. Has an acute illness or temperature ≥ 38.0 °C on any vaccination (ZPIV and priming vaccinations) or within 48 hours of planned vaccination.
 - Subjects with fever or an acute illness on the day of vaccination or in the 3 days prior to vaccination may be re-assessed and enrolled.
 29. In the investigator's opinion, the subject cannot communicate reliably, is unlikely to adhere to study requirements, or has a condition that would limit his or her ability to complete the study.

30. Is unwilling to have their samples collected and stored for future research.

Ages Eligible for Study ⓘ

18 Years to 49 Years (Adult)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

Yes

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

- Primary Purpose ⓘ : Prevention
- Allocation ⓘ : Randomized
- Interventional Model ⓘ : Sequential Assignment
- Masking ⓘ : Double (Participant, Investigator)

Arms and Interventions

Participant Group/Arm i	Intervention/Treatment i
Experimental: ZPIV in Flavivirus-naïve Subjects Two doses of 5.0mcg ZPIV or placebo on Days 1 and 29. N=20 ZPIV, N=5 placebo. Subjects who consent to a third ZPIV dose will receive a 5.0 mcg of ZPIV or placebo on Day 224	Other: Placebo 0.9% Sodium Chloride 5 mcg Biological: Zika Virus Purified Inactivated Vaccine (ZPIV) - Zika Virus Purified Inactivated Vaccine with aluminum hydroxide adjuvant.
Experimental: ZPIV in JEV (IXIARO®) Two 0.5mL doses of IXIARO® (Valneva) Days 1 and 29 followed by two ZPIV or placebo doses will be administered on Days 112 and 140. N=20 ZPIV, N=5 placebo. Subjects who consent to a third ZPIV dose will receive it on Day 336	Biological: IXIARO - An inactivated vaccine indicated for active immunization for the prevention of disease caused by Japanese encephalitis virus (JEV). Other: Placebo 0.9% Sodium Chloride 5 mcg Biological: Zika Virus Purified Inactivated Vaccine (ZPIV) - Zika Virus Purified Inactivated Vaccine with aluminum hydroxide adjuvant.
Experimental: ZPIV in YFV (YF-VAX®)	Other: Placebo 0.9% Sodium Chloride 5 mcg

One 0.5mL dose of YF-VAX® (Sanofi Pasteur) on Day 1 followed by two ZPIV or placebo doses on Days 84 and 112. N=20 ZPIV, N=5 placebo. Subjects who consent to a third ZPIV dose will receive it on Day 308	Biological: YF Vax 17D Strain - A stabilised Yellow Fever Vaccine (Live) that is an injectable suspension of the attenuated 17D strain of yellow fever virus. The vaccine is injected by the subcutaneous route. Biological: Zika Virus Purified Inactivated Vaccine (ZPIV) - Zika Virus Purified Inactivated Vaccine with aluminum hydroxide adjuvant.
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What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Occurrence of SAEs, new onset medical conditions, and AESIs		From Day 1 to Day 658
Occurrence of solicited local AEs		7 days following each ZPIV dose
Occurrence of solicited systemic AEs		7 days following each ZPIV dose

Occurrence of unsolicited AEs		28 days following each ZPIV dose
Relationship of unsolicited AEs to vaccination		28 days following each ZPIV dose
Severity of solicited local AEs		7 days following each ZPIV dose
Severity of solicited systemic AEs		7 days following each ZPIV dose
Severity of unsolicited AEs		28 days following each ZPIV dose

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
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Anti- ZIKV NAbs GMTs by group in subjects who consent to two doses of ZPIV		28 days after each ZPIV dose
Anti- ZIKV NAbs GMTs by group in subjects who consent to two doses of ZPIV		Days 112, 196, 280 and 364 after initial ZPIV dose
Anti- ZIKV NAbs GMTs overall		28 days after each ZPIV dose
Anti- ZIKV NAbs GMTs overall		Days 112, 196, 280 and 364 after initial ZPIV dose
Anti- ZIKV NAbs seroconversion rates by group		28 days after each

in subjects who consent to two doses of ZPIV		ZPIV dose
Anti- ZIKV NAbs seroconversion rates by group in subjects who consent to two doses of ZPIV		Days 112, 196, 280 and 364 after initial ZPIV dose
Anti- ZIKV NAbs seroconversion rates overall		28 days after each ZPIV dose
Anti- ZIKV NAbs seroconversion rates overall		Days 112, 196, 280 and 364 after initial ZPIV dose
Anti-ZIKV Nabs GMTs for group 1 subjects who consent to the third dose of ZPIV		28 days after each ZPIV dose

Anti-ZIKV Nabs GMTs for group 1 subjects who consent to the third dose of ZPIV		Days 112, 196, 224 after initial ZPIV dose
Anti-ZIKV Nabs GMTs for group 1 subjects who consent to the third dose of ZPIV		Days 84, 168 after third ZPIV dose
Anti-ZIKV Nabs GMTs for group 2 and 3 subjects who consent to the third dose of ZPIV		28 days after each ZPIV dose
Anti-ZIKV Nabs GMTs for group 2 and 3 subjects who consent to the third dose of ZPIV		Days 112, 224 after initial ZPIV dose
Anti-ZIKV Nabs GMTs for group 2 and 3 subjects who consent to the		Days 84, 168 after third

third dose of ZPIV		ZPIV dose
Anti-ZIKV Nabs seroconversion rates for group 1 subjects who consent to the third dose of ZPIV		28 days after each ZPIV dose
Anti-ZIKV Nabs seroconversion rates for group 1 subjects who consent to the third dose of ZPIV		Days 112, 196, 224 after initial ZPIV dose
Anti-ZIKV Nabs seroconversion rates for group 1 subjects who consent to the third dose of ZPIV		Days 84, 168 after third ZPIV dose
Anti-ZIKV Nabs seroconversion rates for group 2 and 3 subjects who consent to the third dose of ZPIV		28 days after each ZPIV dose

Anti-ZIKV Nabs seroconversion rates for group 2 and 3 subjects who consent to the third dose of ZPIV		Days 112, 224 after initial ZPIV dose
Anti-ZIKV Nabs seroconversion rates for group 2 and 3 subjects who consent to the third dose of ZPIV		Days 84, 168 after third ZPIV dose

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

National Institute of Allergy and Infectious Diseases (NIAID)

Publications

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

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[Modjarrad K, Lin L, George SL, Stephenson KE, Eckels KH, De La Barrera RA, Jarman RG, Sondergaard E, Tennant J, Ansel JL, Mills K, Koren M, Robb ML, Barrett J, Thompson J, Kosel AE, Dawson P, Hale A, Tan CS, Walsh SR, Meyer KE, Brien J, Crowell TA, Blazevic A, Mosby K, Larocca RA, Abbink P, Boyd M, Bricault CA, Seaman MS, Basil A, Walsh M, Tonwe V, Hoft DF, Thomas SJ, Barouch DH, Michael NL. Preliminary aggregate safety and immunogenicity results from three trials of a purified inactivated Zika virus vaccine candidate: phase 1, randomised, double-blind, placebo-controlled clinical trials. Lancet. 2018 Feb 10;391\(10120\):563-571. doi: 10.1016/S0140-6736\(17\)33106-9. Epub 2017 Dec 5. Erratum In: Lancet. 2020 Jun 20;395\(10241\):1906. doi: 10.1016/S0140-6736\(19\)31427-8.](#)

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Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2016-11-10

First Submitted that Met QC Criteria ⓘ

2016-11-10

First Posted (Estimated) ⓘ

2016-11-15

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2024-04-18

Last Update Posted ⓘ

2024-04-22

Last Verified ⓘ

2017-08-01

More Information

Terms related to this study

Keywords Provided by National Institute of Allergy and Infectious Diseases (NIAID)

Adjuvant
Alum
Inactivated
Purified
Vaccine
Virus
Zika

Additional Relevant MeSH Terms

Virus Diseases
Infections
Mosquito-Borne Diseases
Vector Borne Diseases
Arbovirus Infections
Flavivirus Infections
Flaviviridae Infections
RNA Virus Infections
Zika Virus Infection

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

No

Product Manufactured in and Exported from the U.S.

No