

Record 1 of 1



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Completed ⓘ

Zika Virus Purified Inactivated Vaccine (ZPIV) Accelerated Vaccination Schedule Study (Z001)

ClinicalTrials.gov ID ⓘ NCT02937233

Sponsor ⓘ Kathryn Stephenson

Information provided by ⓘ Kathryn Stephenson, Beth Israel Deaconess Medical Center (Responsible Party)

Last Update Posted ⓘ 2018-08-23

Study Details Tab

Study Overview

Brief Summary

This is a phase 1 trial of one or more administrations of Zika Virus Purified Inactivated Vaccine (ZPIV). The trial will be conducted under a placebo controlled, double-blind, randomized allocation of study product. There are four groups in the study. Each group is testing a different vaccine schedule.

Official Title

A Phase 1, Randomized, Double-Blind Placebo-Controlled Clinical Trial to Evaluate the Safety and Immunogenicity of an Accelerated Vaccination Schedule With a Zika Virus Purified Inactivated Vaccine Plus Alum Adjuvant in Healthy Adults

Conditions ⓘ

Feedback

Zika

Intervention / Treatment ⓘ

- Biological: Zika Virus Purified Inactivated Vaccine
- Other: Placebo

Other Study ID Numbers ⓘ

- 2016P000268

Study Start (Actual) ⓘ

2016-12-08

Primary Completion (Actual) ⓘ

2018-06-04

Study Completion (Actual) ⓘ

2018-06-04

Enrollment (Actual) ⓘ

36

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

Massachusetts Locations

 **Boston, Massachusetts, United States, 02215**
Center for Virology and Vaccine Research
Clinical Trials Unit, Beth Israel Deaconess
Medical 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. Age 18-50 years old.
2. Ability and willingness to provide informed consent.
3. Assessment of understanding: completion of a questionnaire prior to first screening procedure; verbally demonstrate understanding of all questionnaire items answered incorrectly.
4. Available for the duration of the trial.
5. Good general health as shown by medical history, physical exam, and screening laboratory tests.
6. The following laboratory parameters:
 - Hematology
 - Hemoglobin ≥ 10.5 g/dL for women; ≥ 11 g/dL for men
 - Absolute Neutrophil Count (ANC): $\geq 1000/\text{mm}^3$
 - Platelets: 125,000 to 550,000/ mm^3
 - Chemistry
 - Creatinine: $< 1.1 \times$ upper limit of normal (ULN)
 - AST: $< 1.25 \times$ ULN
 - ALT: $< 1.25 \times$ ULN
 - Normal urinalysis
 - Negative urine glucose.
 - Negative or trace urine protein.
 - Negative or trace urine hemoglobin (if trace hemoglobin is present on dipstick, a microscopic urinalysis within institutional range).
7. All female participants must be willing to undergo serum or urine beta human chorionic gonadotropin pregnancy tests at time points indicated in the Schedule of Procedures and must test negative prior to vaccination.
8. All sexually active males (unless anatomically sterile) must be willing to use an effective method of contraception (such as consistent condom use) from the day of first vaccination until Week 12.
9. If a woman of child-bearing potential, committed to use an effective method of contraception when sexually active with men until Week 12, including:
 - Condoms (male or female) with or without spermicide.
 - Diaphragm or cervical cap with spermicide.
 - Intrauterine device.
 - Hormonal contraception.
 - Successful vasectomy in the male partner (considered successful if a woman reports that a male partner has [1] documentation of azoospermia by microscopy, or [2] a

vasectomy more than 2 years ago with no resultant pregnancy despite sexual activity post-vasectomy).

- Not be of reproductive potential, such as having undergone hysterectomy, bilateral oophorectomy, or tubal ligation.

Exclusion Criteria:

1. History of known flavivirus infection or previous receipt of flavivirus vaccine.
2. Positive serology for HIV-1, Hepatitis B surface antigen, or anti-hepatitis C virus antibodies prior to enrollment.
3. Planned travel to areas with active Zika virus transmission during the study period.
4. Recent (within 3 weeks) travel to an area with active Zika virus transmission.
5. Current or planned participation in another clinical trial of an experimental agent during the study period.
6. Pregnant or lactating.
7. Any condition, including any clinically significant acute or chronic medical condition, for which, in the opinion of the investigator, participation would not be in the best interest of the subject (eg, compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments.
8. Use of anticancer, antituberculosis or other medications considered significant by the investigator within the previous 6 months.
9. Receipt of live-attenuated vaccine within the previous 60 days or planned receipt within 60 days after vaccination with Investigational Product (within 14 days for live attenuated influenza vaccine [LAIV]); or receipt of other vaccine (e.g., influenza, pneumococcal), allergy treatment with antigen injections or tuberculin skin test within the previous 14 days or planned receipt within 14 days after vaccination with Investigational Product
10. Receipt of blood transfusion or blood-derived products within the previous 3 months.
11. Previous severe local or systemic reactions to vaccination.
12. History of splenectomy
13. History of seizure in the last 3 years (participants with a history of seizures who have neither required medications nor had a seizure for 3 years are not excluded)
14. Known autoimmune disease
15. Asthma other than mild, well-controlled asthma. Exclude participants who:
 1. Use a bronchodilator (beta 2 agonist) daily, or
 2. In the past year have (any of the following):
 - i. Had > 1 exacerbation of symptoms treated with oral steroids
 - ii. Routinely used moderate to high dose inhaled corticosteroids (e.g., more than the equivalent of 250 mcg fluticasone; 400 mcg budesonide; 500 mcg beclomethasone; or 1000 mcg triamcinolone/flunisolide, as a daily dose) or theophylline
 - iii. Needed emergency care, urgent care, hospitalization, or intubation for asthma
 - c. Prophylactic bronchodilator use prior to exercise is not exclusionary
16. Diabetes mellitus type 1 or type 2, including cases controlled with diet alone. (Not excluded: history of isolated gestational diabetes.)

17. Thyroidectomy, or thyroid disease requiring medication during the last 12 months
18. Angioedema within the last 3 years if episodes are considered serious or have required medication within the last 2 years
19. Uncontrolled Hypertension:
 1. If a person has been diagnosed with hypertension during screening or previously, exclude for hypertension that is not well controlled. Well- controlled hypertension is defined as blood pressure consistently ≤ 140 mm Hg systolic and ≤ 90 mm Hg diastolic, with or without medication, with only isolated, brief instances of higher readings, which must be ≤ 150 mm
 2. If a person has NOT been diagnosed with hypertension during screening or previously, exclude for systolic blood pressure ≥ 150 mm Hg at enrollment or diastolic blood pressure ≥ 90 mm Hg at enrolment
20. Bleeding disorder diagnosed by a doctor (e.g. factor deficiency, coagulopathy, or platelet disorder requiring special precautions)
21. Malignancy (Not excluded: a participant with a surgical excision and subsequent observation period that in the investigator's estimation has a reasonable assurance of sustained cure or is unlikely to recur during the study period)
22. Psychiatric condition that compromises safety of the participant or precludes compliance with the protocol, specifically excluding persons with psychoses within the past 3 years, ongoing risk for suicide, or history of suicide attempt or gesture within the past 3 years

Ages Eligible for Study

18 Years to 50 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 ⓘ : Parallel Assignment

Masking ⓘ : Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: 4 Week Schedule Zika Purified Inactivated Vaccine 5 mcg (or placebo) IM at Week 0 and Week 4	Biological: Zika Virus Purified Inactivated Vaccine Other: Placebo
Experimental: 2 Week Schedule Zika Purified Inactivated Vaccine 5 mcg (or placebo) IM at Week 0 and Week 2	Biological: Zika Virus Purified Inactivated Vaccine Other: Placebo
Experimental: Single Vaccination Schedule Zika Purified Inactivated Vaccine 5 mcg (or placebo) IM at Week 0 only	Biological: Zika Virus Purified Inactivated Vaccine Other: Placebo

What is the study measuring?

Primary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Incidence, intensity, and relationship to vaccination of solicited local and systemic adverse events		7 days following each vaccination
Incidence, intensity, and relationship to vaccination of unsolicited local and systemic adverse events		28 days following each vaccination
Incidence, intensity, and relationship to vaccination of serious local and systemic adverse events		365 days following each vaccination

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
ZIKV microneutralization		28 days following

Log10 MN50 titers		last vaccination, and at 6 months
Zika Env-specific Log10 endpoint ELISA titers		28 days following last vaccination, and at 6 months
Zika Plaque reduction neutralization test titer		28 days following last vaccination, and at 6 months
IFN-γ ELISPOT responses to prM, Env, Cap, and NS1 peptides		28 days following last vaccination, and at 6 months

Collaborators and Investigators

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

Sponsor ⓘ

Kathryn Stephenson

Collaborators ⓘ

- Walter Reed Army Institute of Research (WRAIR)

- 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.

- [Stephenson KE, Tan CS, Walsh SR, Hale A, Ansel JL, Kanjilal DG, Jaegle K, Peter L, Borducchi EN, Nkolola JP, Makoni T, Fogel R, Bradshaw C, Tyler A, Moseley E, Chandrashekar A, Yanosick KE, Seaman MS, Eckels KH, De La Barrera RA, Thompson J, Dawson P, Thomas SJ, Michael NL, Modjarrad K, Barouch DH. Safety and immunogenicity of a Zika purified inactivated virus vaccine given via standard, accelerated, or shortened schedules: a single-centre, double-blind, sequential-group, randomised, placebo-controlled, phase 1 trial. Lancet Infect Dis. 2020 Sep;20\(9\):1061-1070. doi: 10.1016/S1473-3099\(20\)30085-2. Epub 2020 May 6.](https://pubmed.ncbi.nlm.nih.gov/32618279/) (https://pubmed.ncbi.nlm.nih.gov/32618279/)
- [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.](http://pubmed.ncbi.nlm.nih.gov/29217375/) (http://pubmed.ncbi.nlm.nih.gov/29217375/)

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 ⓘ

2016-10-12

First Submitted that Met QC Criteria ⓘ

2016-10-17

First Posted (Estimated) ⓘ

2016-10-18

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2018-08-22

Last Update Posted ⓘ

2018-08-23

Last Verified ⓘ

2018-08

More Information

Terms related to this study

Keywords Provided by Kathryn Stephenson, Beth Israel Deaconess Medical Center

Zika
Vaccine
ZPIV

Additional Relevant MeSH Terms

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

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Undecided