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CoVPN 3002 A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222 for the Prevention of COVID-19 LAB

Project Number
3UM1AI068618-14S2

Former Number
3UM1AI068618-14S1

Contact PI/Project Leader
MCELRATH, MARGARET JULIANA

Awardee Organization
FRED HUTCHINSON CANCER RESEARCH CENTER

Abstract Text

This proposal outlines the scientific agenda for the **COVID**-19 Prevention Network (CoVPN) Vaccines Leadership Operations Center (LOC) for implementation of the first **COVID**-19 **vaccine** efficacy trial "A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, A Non-replicating ChAdOx1 Vector **Vaccine**, for the Prevention of **COVID**- 19." With the global **COVID**-19 pandemic, we recognize a significant need for vaccines that modify **COVID**-19 in SARS-CoV-2 infected individuals. Addressing this gap, the National Institute of Health (NIH) led rapid constitution of the CoVPN, partnering 5 NIH supported clinical trial networks, to create an enhanced network of physician scientists at 64 United States (US) and 55 international clinical trial sites in 15 countries dedicated to developing globally effective vaccines for SARS-CoV-2. Due to its extensive experience implementing global HIV **vaccine** trials over the last 20 years, the HIV **Vaccine** Trials Network (HVTN) LOC was selected as the LOC for CoVPN **vaccine** trials. This trial, a phase 3, placebo-controlled, double-blinded study will test the efficacy of AZD1222, a recombinant replication-defective chimpanzee adenovirus expressing the SARS-CoV-2 spike (S) surface glycoprotein, to modify **COVID**-19 disease in adults 18 year of age and older. Participants will be recruited from up to 100 clinical trial sites across the US, using data analytics to target high risk individuals with a diverse racial and ethnic profile. Participants will receive symptomatic screening for SARS-CoV-2 infection, and if they become infected will be monitored with frequent clinical check-ins and remote monitoring of vital signs. Infected individuals who progress to moderate-severe **COVID**-19 will be referred for hospitalization. All trial endpoint assays will be done at CoVPN laboratories, using qualified and validated assays for diagnosis and immune monitoring. Specific aims of this study are to demonstrate efficacy of AZD1222 to prevent **COVID**-19, to evaluate the safety, tolerability and reactogenicity of 2 injections given 4 weeks apart, to assess the ability to prevent infection with SARS-CoV-2, to assess the ability to modify **COVID**-19 disease, to assess the ability to prevent emergency room visits, and to evaluate the binding and neutralizing antibody responses. This efficacy trial will tell us much about the adaptive immune response in persons who receive a SARS-CoV-2 S protein based **vaccine** and about their ability to modify the disease course of **COVID**-19. In addition, it will improve our understanding of the dynamics and duration of these responses and will inform rational design and testing of preventive and therapeutic monoclonal antibody interventions. Lastly, the results of this trial will be used to assess registration of this **vaccine** product as well as to modify future **COVID**-19 **vaccine** trials planned over the next 12 months.

Public Health Relevance Statement

Project Narrative The outbreak of SARS-CoV-2 across the globe presents an unprecedented health risk to the world's population and requires intensive study of key gaps in our understanding of the immune response and what adaptations lead to protective immunity. In this study, the CoVPN will apply its world class laboratory, biostatistical and vaccine trial leadership expertise to assess this response in 30,000 persons at up to 100 clinical trial sites across the US. The goal of this protocol is to rapidly assess the efficacy of AZD1222, a non- replicating ChAdOx1 vector vaccine, to modify the severity of COVID-19 disease in SARS-CoV-2 infected individuals. Title A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19

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Project Number
3UM1AI068618-14S2

Former Number
3UM1AI068618-14S1

Contact PI/Project Leader
MCELRATH, MARGARET JULIANA

Awardee Organization
FRED HUTCHINSON CANCER RESEARCH CENTER

Read More

Details

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UNITED STATES (US)

Department Type
Unavailable

Organization Type
Research Institutes

State Code
WA

Congressional District
07

Other Information

FOA
PA-18-591

Study Section

Fiscal Year
2020

Award Notice Date
03-September-2020

Administering Institutes or Centers
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DUNS Number
078200995

CFDA Code
855

Project Start Date
04-September-2020

Project End Date
30-November-2021

Budget Start Date
04-September-2020

Budget End Date
30-November-2021

Project Funding Information for 2020

Total Funding
$6,554,653

Direct Costs
$6,082,040

Indirect Costs
$472,613

Year	Funding IC	
2020	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	$6,554,653

Thank you for your feedback!

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3UM1AI068618-14S2	3UM1AI068618-14S1	MCELRATH, MARGARET JULIANA	FRED HUTCHINSON CANCER RESEARCH CENTER

Patents

No Patents information available for 3UM1AI068618-14S2

Outcomes

The Project Outcomes shown here are displayed verbatim as submitted by the Principal Investigator (PI) for this award. Any opinions, findings, and conclusions or recommendations expressed are those of the PI and do not necessarily reflect the views of the National Institutes of Health. NIH has not endorsed the content below.

No Outcomes available for 3UM1AI068618-14S2

Clinical Studies

No Clinical Studies information available for 3UM1AI068618-14S2

News and More

Related News Releases

No news release information available for 3UM1AI068618-14S2

History

No Historical information available for 3UM1AI068618-14S2

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No Similar Projects information available for 3UM1AI068618-14S2