



BRIGHAM AND WOMEN'S HOSPITAL



HARVARD MEDICAL SCHOOL  
IRB Approved at the  
Protocol Level  
Jun 24, 2021

#31213340.1

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**Paul M Ridker, MD, MPH**

*Eugene Braunwald Professor of Medicine  
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*Director, Center for Cardiovascular  
Disease Prevention*

June 17, 2021

Dear ACTIV-4B Trial Participant,

On behalf of the National Heart, Lung, and Blood Institute, I write to personally thank you for your participation in the ACTIV-4B COVID-19 Outpatient Thrombosis Prevention Study. Your willingness to help all of us learn how to best care for COVID-19 outpatients during the pandemic and our time of national need has been crucial to our success.

**I write now to let you know that the trial has come to an early end and thanks to your participation in the study we have learned something very important for patient care.** Simply put, the number of blood clot problems we are seeing in the study is very low and does not justify any continuation of treatment: after looking at the data carefully, we are convinced that the best course of action for clinically stable COVID-19 outpatients like yourself does not justify any possible risks associated with blood thinning therapies. In other words, even though the risk of treatment has also turned out to be very low, the best option with regard to preventing blood clots in your situation seems to be no treatment at all.

Please be aware that this does not pertain to many other situations where antiplatelet (such as aspirin) and anticoagulant (blood thinners such as coumadin or warfarin) therapy is being prescribed; it only pertains to the use of these kinds of drugs within the context of the ACTIV-4B outpatient trial.

**If you are still taking study medications, we ask that you stop doing so at this time.** Over the next few days, you will be contacted by our study team who will let you know how to send back any leftover drug you may have. The study team will also check in with you by phone to see how you are doing and answer any questions you may have. Any decisions about your care should be made according to the judgment of your primary care physician.

You were one of more than 600 people in the United States who volunteered to join the ACTIV-4B study. I hope you take considerable pride in helping to answer such an important question with broad public health implications for many patients who, like you, have been infected with COVID-19 but are clinically stable and recovering at home.

As a physician, we sometimes discover that the best thing we can do for our patients is less, not more. Dr. Bernard Lown, an internationally renowned doctor, Nobel Peace Prize recipient, and mentor of mine once said "Do as much as possible for the patient, and as little as possible to the patient". That is an excellent summary of what we now know.

On behalf of our team, please accept our enormous thanks for your time, commitment, and courage to help during our national crisis. Your efforts have taught all of us something very important for patient care.

Sincerely yours,

Paul M Ridker, MD

Trial Chairman, ACTIV-4B

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