

- WHAT ARE THE COSTS?

The study drug or placebo will be provided free of charge, and all research MRI scans and laboratory tests, other than those needed for routine clinical care. Additionally, study subjects will be provided a cash stipend to help defray travel expenses for trial related visits. Routine clinical care costs are not covered by the trial.

“There is a pressing need to know whether statins are safe or helpful after bleeding from cavernous angiomas...”

Connie Lee, Psy.D Angioma Alliance

The trial is supported by the National Institute of Neurological Disorders and Stroke, of the United States National Institutes of Health.



If you are interested in participating in the trial, please discuss this with your doctor and call our trial nurse for pre-screening.

Contact Us

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WHY IS THIS STUDY BEING DONE?

This study will look at the effect of atorvastatin on reducing the chance of future bleeds from cerebral cavernous malformations, also known as cavernous angiomas (CA), which have recently bled.

While many CAs do not cause any symptoms, those lesions that have caused a definite symptomatic hemorrhage (bleed) are known to cause more problems, with a high risk of re-bleeding, greatest in the first 2 years following hemorrhage (bleeding).

Currently no medication exists to prevent CA bleeding. Animal studies have shown evidence of reduced bleeding and lesion growth with atorvastatin study drug: Atorvastatin, the drug used in the study, is a statin drug, generally used to help lower cholesterol. Among statins approved by the FDA, atorvastatin is generally well tolerated clinically at the doses needed to see the ideal effect on CAs.

This research will study the effect of a two year course of atorvastatin on bleeding in CAs that bled with clinical symptoms during the previous year. Patients may receive placebo or atorvastatin and will be watched clinically and by highly specialized MRI techniques at the University of Chicago Medicine. Positive results of this trial will encourage further testing of atorvastatin and similar drugs in humans.



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Atorvastatin Therapy in Cavernous Angiomas with Symptomatic Hemorrhage Exploratory Proof of Concept (AT CASH EPOC) Trial

Does Statin Therapy Stabilize Cavernous Angiomas After Recent Bleed ?

Trial Co Chairs
Pr. Issam Awad, MD
University of Chicago Medicine
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Johns Hopkins Medical Institutions



Brain Injury OutcomeS
Clinical Trial Coordinating Center



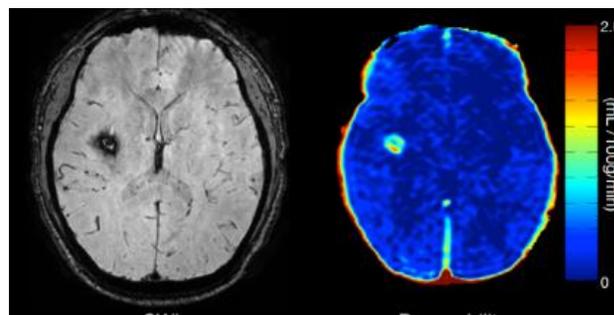
clinicaltrials.gov: NCT02603328



WHAT IS INVOLVED IN THE STUDY?

Your first visit to University of Chicago will involve obtaining consent, reviewing your medical history, and a physical and neurological examination. This will be followed by blood tests, and you will have your baseline research MRI scan. If you are found to be eligible for this trial, you will be randomly assigned to receive either study drug or placebo (a non-active pill, basically a sugar pill) for the duration of the trial. **You will continue to receive care by your referring physicians and primary care doctor. Your treating doctors, the researchers involved and you will not know if you are receiving the drug or placebo.**

You will be followed for 2 years after you start taking the drug. Regardless of what group you are assigned to, you will take a same colored capsule daily and keep a record of your dose. You will be asked to obtain blood work through your local doctor after 3 months, and return to the clinic at 12 and 24 months after enrollment. At these visits, you will have an MRI done to evaluate your response to study drug. These trial related MRI scans are different from the scans available in the community, as they examine leakage and bleeding in the CA.



Research MRI scan images (lesion shown on left side of each image)

WHO CAN JOIN THE TRIAL?

You may qualify if you are 18-80 years of age and have a diagnosis of a cerebral cavernous malformation, also known as cavernous angioma (CA) of the brain, with evidence of a confirmed symptomatic hemorrhage within the past year. You must have not been on statin (a type of drug used to lower cholesterol) therapy during the twelve months preceding enrollment.

Your CA lesion would need to have been evaluated for possible surgery after the recent bleed, and you and your physician elected at the time not to undergo surgery. Due to the nature of the drug used in the trial and the safety prerequisites for MRI scans, you will not be able to enroll if you have/are:

- Pregnant
- Previous brain irradiation
- Kidney disease
- Liver disease
- Muscle Disease

To be enrolled in the trial you should have a regular primary care physician and have valid healthcare insurance. You cannot be using statins for cholesterol or cardiovascular indications. If you agree to participate in this study, we will ask you to do the following things:

If you experience any side effects from the drug, you may be considered for lower dose or may be asked to stop the drug altogether. If you experience a bleed during the trial, we will review your locally obtained MRI or see you at University of Chicago Medicine, and we would ask you to stop the drug. If you stop the drug, we will still follow you for the 2-year duration of the study, including research MRI scans

WHAT ARE THE RISKS?

Millions of people around the world are taking statins for various medical conditions, the drug is usually very well tolerated. The most common side effect is muscle pain. Other risks include diarrhea, upset stomach, slight changes in kidney and liver function tests, tiredness, confusion, bloating. Other rare but serious side effects include muscle inflammation, type 2 diabetes, and kidney or liver dysfunction.

Contrast-enhanced MRI and blood draws will be provided at University of Chicago Medicine. These are standard clinical procedures and have minimal risk. The trial includes several experts who will monitor you and other subjects, to make sure that the drug will not increase your risk of bleeding or problems from the CA.