

**Short Title:** Efficacy and Safety of BAF312 Compared to Placebo in Patients With Intracerebral Hemorrhage (ICH).

**BAF312: A phase II, patient- and investigator-blinded, randomized, placebo-controlled study to evaluate efficacy, safety and tolerability of BAF312 (siponimod) in patients with stroke due to intracerebral hemorrhage (ICH)**

**IRB/UVA Tracking #:** 21006

**Principal Investigator:** Javier Provencio, MD

**Contact First Name:** Heather

**Contact Last Name:** Haughey

**Contact Email:** hmh8f@virginia.edu

**Contact Phone:** 434-243-8065

**Official Trial Title:** A phase II, patient- and investigator-blinded, randomized, placebo-controlled study to evaluate efficacy, safety and tolerability of BAF312 (siponimod) in patients with stroke due to intracerebral hemorrhage (ICH)

### **Study Description**

The University of Virginia's Department of Neurology is currently enrolling people who have suffered a stroke caused by an intracerebral hemorrhage (ICH; brain bleed stroke) for a research study supported by the pharmaceutical company Novartis. The purpose of the research study is to investigate the initial efficacy and safety of a new investigational medication BAF312, when administered on top of standard-of-care compared to placebo in patients with stroke due to ICH. BAF312 is a drug that could potentially limit brain inflammation and subsequent brain edema after ICH, and thereby improve neurological outcomes for hemorrhagic stroke patients.

The study will enroll 60 patients with a confirmed diagnosis of supratentorial intracerebral hemorrhage. Patients will be evaluated for eligibility within 22 hours of symptom onset (last seen normal). Participants have a 50% chance of receiving the study drug BAF312 and a 50% chance of receiving placebo. Study drug or placebo will be supplied intravenously for days 1 through 7, after which an oral dose (tablets) will be taken for days 8 through 14. After discharge from the hospital, participants will enter a 3-month follow-up phase, with clinic visits on days 14, 30 and 90 post-stroke. Vitals, labs, and other assessments will be collected during these visits.

Participants must be between the age of 18 and 85 years (inclusive) and must have had the onset of ICH witnessed and/or last seen healthy no longer than 24 hours prior to enrollment in the study.

This study is actively enrolling participants. To learn more information, please visit <https://clinicaltrials.gov/ct2/show/NCT03338998> or contact the Clinical Trial Manager: Heather M. Haughey, Ph.D. by phone 434-243-8065 or email hmh8f@virginia.edu.

**Compensation:** No compensation