Study Protocol: Glibenclamide in Aneurysmatic Subarachnoid Hemorrhage (GASH)

The authors have no disclosures to report.

I acknowledge my continuing obligation to disclose to AANS/NREF/NPA, promptly and in writing, any change in my circumstances. I further acknowledge that if there is any case where my private interest conflict with the interests of AANS/NREF/NPA, I will indicate that I may have a conflict and abstain from any vote, speaking engagement, planning related to that issue.
Recent findings on the benefits of glibenclamide, like significant reduction on the mortality rate to 5% in models of ischemic stroke and brain trauma, started a new era for prospective studies on sulfonylureas. The effect of glibenclamide was also examined in a model of subarachnoid hemorrhage, with findings of significantly reduced ZO-1 abnormalities, resulting in less edema formation and considerably reduced transynaptic apoptosis of hippocampal neurons, reduced venous congestion and significantly ameliorated impairments in spatial learning. Based on this data, the authors have elaborated the first clinical trial to establish glibenclamide’s evidence as an adjunct treatment in aneurysmal subarachnoid hemorrhage.
Objectives: To evaluate the role of glibenclamide in the clinical outcome of patients with aneurysmal subarachnoid hemorrhage and assess its safety and effect in mortality rate, quality of life and cognitive performance. Study Design: A randomized, double-blind and prospective trial meant to evaluate the use of glibenclamide on acute aneurysmal subarachnoid hemorrhage.
Methods

Patients will be allocated randomly in two groups, one for 0.5 mg daily intake of glibenclamide for 21 days and another for control with placebo. General clinical data and late cognitive status will be accessed in both groups.
Expected Outcomes

The primary outcome will be the distribution of modified Rankin Scale (mRS) scores assessed at 6 months. Secondary outcomes will be death at 6 months, delayed ischemic deficits, occurrence of serious adverse events attributable to medication, cognitive assessment and quality of life as measured by the SF-36 questionnaire.