Wednesday, February 12, 2014, 10:30 am - 12:00 noon

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Presentation Number: LB1

Publishing Title: The Urico-ictus Study: A Randomized Trial of Efficacy and Safety of Uric Acid Administration in Acute Stroke

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Abstract Body:

BACKGROUND Uric acid is an endogenous antioxidant molecule that is neuroprotective in experimental brain ischemia. We assessed whether it would improve functional outcome in patients with ischemic stroke.

METHODS The URICO-ICTUS was a double-blind, placebo-controlled trial of acute ischemic stroke patients treated with alteplase within 4.5 hours of symptoms onset in 10 Spanish sites. Patients were randomly assigned to receive in an 1:1 fashion an infusion of placebo or uric acid manufactured according to Good Manufacturing Procedures. The primary end point of the trial was the proportion of patients with a favorable outcome at 90 days, indicating a modified Rankin scale (mRS) of 0 to 1, or a mRS of 2 in patients with a prior qualifying mRS score of 2. Safety end points included death, symptomatic intracranial hemorrhage, and gouty attacks. All randomized patients defined the Intention To Treat population, and those with a correct diagnosis of stroke who had initiated the study medication, defined the modified Intention To Treat population, which was used for the main efficacy analysis. A Data Blind Review was performed before the lock of the database and the opening of randomization codes. Rates and Risk Ratios (RR) were estimated using a log-binomial regression model that included the treatment and the factors used to stratify the assignment (Stroke severity at baseline, and Center). Shift changes on the modified Rankin scale were also performed using a proportional odds model and non-parametric methods.

RESULTS Patients were enrolled into the study from July 1st, 2011, to April 30, 2013. Of 1129 thrombolysed patients screened during the trial, 421 were randomized, and 411 formed the modified Intention To Treat population, including 211 receiving uric acid, and 200 receiving placebo. Sixty patients died, and 7 were lost for follow up. Mean (standard deviation) age was 73.7 (11.8) year, median (interquartile range) admission NIHSS score was 13.00 (9.00, 18.00), and 50 percent were men. The two study groups were well balanced with respect to baseline prognostic variables. Results on the primary outcome, secondary outcomes, and relevant subgroup effects will be presented during the conference.
Author Disclosure Block: