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Upstream therapeutic strategies of Valsartan and Fluvastatin on hypertensive patients with non-permanent Atrial Fibrillation (VF-HT-AF): Study protocol for a randomized controlled trial

Wenwei Qi, Tong Liu, Gang Xu, Yingzi Liang, Lifeng Li, Lan Ye and Guangping Li Tianjin Medical University, China

**Background:** Previous studies regarding rhythm control in patients with Atrial Fibrillation (AF) could not demonstrate the enough efficacies of available anti-arrhythmic drugs. The "upstream therapy" has emerged as a potential strategy for the prevention and treatment of AF. The use of angiotensin II receptor blockers (ARBs) and statins have been suggested to decrease new-onset AF in previous studies but which have remained inadequately explored. This study was designed to examine whether valsartan and or fluvastatin can reduce the probability of non-permanent AF in patients with hypertension.

Methods/Design: The VF-HT-AF study is a multicenter, randomized, open-label, four-arm parallel group study with comparative evaluation of valsartan and fluvastatin as upstream therapies for the patients with non-permanent AF complicated hypertension. The primary endpoint is the difference in the development of paroxysmal AF into persistent and or permanent AF, persistent AF into permanent AF as well as the incidence of overall and persistent AF recurrence which are evaluated by 7-days ambulatory electrocardiograph monitoring (Holter) and patients' diaries during 2 years follow-up. The secondary endpoints of this study include: (1) Fatal and nonfatal myocardial infarction; (2) Heart failure (NYHA III or IV); (3) Cardiogenic shock; (4) Serious bleeding which need to be hospitalization; (5) Malignant ventricular arrhythmia (including ventricular tachycardia and or fibrillation); (6) Revascularization therapy (CABG/PCI); (7) Radiofrequency catheter ablation of AF; (8) The changes of left atrial dimension on ultrasound echocardiography; (9) Stroke; (10) Cardiovascular mortality; and (11) All-cause mortality. The study will follow 1879 hypertensive patients with non-permanent AF who are treated at 15 medical centers throughout China and will provide available or useful clinical information.

**Discussion:** The proposed study, evaluating the impact of implementing valsartan and or fluvastatin treatment on non-permanent AF is the first study in hypertensive patients complicated non-permanent AF in Chinese population. Results of this study will contribute to the upstream therapies of AF.

qiwenwei2008@163.com

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