THE KOREAN SOCIETY OF NEPHROLOGY
APCN & KSN 2024
June 13(Thu) - 16(Sun), 2024 Coex, Seoul, Korea
APSN
Promoting Sustainable Kidney Health: The Asia-Pacific and Beyond

Abstract Submission No.: A-0658

A prospective registry to evaluate safety and efficacy of Hativ electrocardiogram monitoring on patients with hemodialysis

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Objectives : The high mortality rate and costs of patients with end-stage renal disease (ESRD) are a medical and socio-economic burden, so managing their risk factors is very important. Recently, artificial intelligence (AI)-based electrocardiogram (ECG) analysis technology has made it possible to detect cardiovascular diseases using only ECGs by distinguishing minute differences in electrical currents in the heart that are difficult for humans to read, and active verification of its clinical effectiveness is in progress.
Methods : In this study, using Hativ®, a currently commercially available class II medical device, ECGs are measured every day at home and before and after dialysis. Additionally, ECGs are measured when chest discomfort or unusual symptoms were present, and the corresponding symptoms are monitored. It targets patients with smartphones over the age of 19 who are receiving maintenance hemodialysis for more than 3 months due to ESRD and excludes those with intracardiac electrodes and devices. Demographic characteristics, medications, blood tests, and echocardiography results are collected, and the results of additional questionnaires or cardiac tests are monitored for up to 3 months. During the study period, if there are any critical abnormalities or symptoms on the ECGs, the medical staff or the subject may request additional treatment.
Results : This study is scheduled to be conducted for one month starting in March 2024.
Conclusions : By measuring ECGs before and after hemodialysis, we aim to obtain data on the frequency and type of arrhythmia, confirm the relationship between cardiovascular disease and dialysis intervals. We will also apply an AI-based ECG analysis model to the measured ECGs to determine the association with the mortality rate. Furthermore, we plan to establish a basis for using AI analysis technology combined with a portable ECG device in the management of patients with ESRD and conduct follow-up research to improve prognosis.