

Amendment to Ancillary Study Proposal – 2014.18_Chen

Significance of Atrial Fibrillation and Atrial Fibrillation Burden Detected by Novel ECG Monitoring in Community-Dwelling Elderly – R01HL126637

1.1. Proposed amendment

We propose to apply the Zio XT Patch for 2 weeks of heart rhythm monitoring in 600 ARIC participants during Visit 7.

As of December 6, 2017, we have enrolled 2,643 participants for 2 weeks of heart rhythm monitoring.

1.2. Protocol change

This project will be conducted at Minneapolis, Washington County, and Jackson Field Centers.

We propose to apply the Zio XT Patch for 2 weeks of heart rhythm monitoring on 2 subgroups of participants during Visit 7. The timeline will be March 1, 2018 through June 30, 2019.

a) Participants with frequent supraventricular tachycardia (SVT) episodes or high premature atrial contraction (PAC) burden and without known AF or AF on Zio XT Patch during Visit 6

We plan to invite 800 participants with the highest frequency of SVT or PAC burden >5% to undergo 2 weeks of heart rhythm monitoring during Visit 7. We aim to enroll 550 participants.

b) Participants with AF burden of <100% on Zio XT Patch during Visit 6

We plan to invite all participants with AF burden <100% to undergo 2 weeks of heart rhythm monitoring during Visit 7. It is estimated that the total number of eligible participants will be approximately 80 participants and we aim to enroll 50 participants.

1.3. Aims

a) Participants with frequent SVT episodes or high PAC burden

Our aims are to: (1) Define proportion who will progress to AF, (2) Identify risk factors for progression to AF.

b) Participants with paroxysmal AF burden <100%.

Our aims are to: (1) Define determinants of progression to high AF burden, (2) Evaluate association of change in AF burden with outcomes such as cognitive change.

1.4. Procedure

- Lin Yee Chen (PI) will send a list of eligible participants to the Field Centers.
- There should be at least 1 year between the Zio Patch during Visit 6 and the Zio Patch during Visit 7.
- Field Center staff will call eligible participants to invite them to participate.
- Field Center staff will apply the Zio Patch on participants when they present in clinic for Visit 7. For participants who would like or need to have the Zio Patch applied on another day, Field Center staff will provide the Zio Patch to participants who will apply the patch themselves, guided by phone call with Field Center staff.
- For participants who refuse to come in for V7, it is not an automatic refusal for the Zio Patch. For these participants, consent will be obtained over the phone and the ZIO questionnaire will be administered over the phone. Field Center staff will mail the device to participants who will apply the device themselves at home. Self-application of the device will be guided by phone call with Field Center staff.
- Field Center staff will make Day 3 and Day 10 phone calls (as per current protocol).
- Zio Patch must not be worn at the time of CT and MRI scans.
- Participants will be reimbursed \$25 for wearing the Zio XT Patch for 2 weeks.