

### **Study Aim – Why the study was carried out.**

Many hypertensive patients fail to achieve the recommended blood pressure targets, because either the medication doesn't work, or the patient gets side effects from the medication. Alternative treatments for this 'uncontrolled' blood pressure (BP) are expensive and invasive.

The main aim of the SCRATCH-HTN early phase study was to test whether a new non-invasive device treatment could be safe and acceptable to patients, and whether it may help lower BP in patients with uncontrolled high BP.

This was done using the AffeX-CT device, which provided a very small electrical current to the ears. This treatment method is known as transcutaneous autonomic neuromodulation (tAN), and it can stimulate the nerves that control BP. We also wanted to see if the study subjects thought the device was safe, easy to use and acceptable.

### **Study Methods – What the researchers did.**

Eligible participants self-administered the device treatment (active tAN or sham-tAN) using clips attached to a specific part of the ear (the tragus) for 30 minutes a day for 14 days, then once a week for 10 further weeks. This means that the treatment period was 3 months in total. During these 3 months, other tests were done to capture data for the trial, such as Office BP and 24-hour ambulatory blood pressure monitoring (ABPM) to measure BP and heart rate, electrocardiogram (ECG), echocardiogram (ECHO), and questionnaires for quality of life and sleep quality.

### **Study Results – What the researchers found.**

Of 170 subjects screened to take part in the study, 63 subjects were randomly assigned in a 2:1 ratio to either an active device or a sham (inactive) device which looks like an active device but does not provide any real treatment. This means 41 subjects were given an active device, and 22 subjects were given a sham (inactive) device. Only two subjects (who were in the sham device group) did not complete their treatment, so the final data analysis included 61 subjects.

The average age of these subjects was 47.7 years, and 44 (72.1%) of the 61 patients were male. The average daytime BP at baseline, as measured by 24-hour ABPM, was 150/95 mmHg. Most subjects were already treated on average with 2 blood pressure-controlling drugs (range between 1 and 4 medications).

At the end of the study, subjects from both active and sham groups showed improvements in BP as compared to their baseline BP. However, there was no statistical difference in BP at the end of the study (after 3 months treatment) between the two groups. There were also no significant differences between the two groups in the change in other measures, such as heart rate, quality of life or sleep quality.

It was observed that subjects with higher systolic BP (greater than 160 mmHg) at the start of treatment showed a significantly greater reduction in systolic BP following active device treatment, as compared to those randomly allocated to the sham arm.

The trial subjects in both groups said that the device was easy to use and compliance with the device treatment regimen (number of days the device was used) was very good. Regarding device safety, there were no serious adverse events reported indicating that the device is safe and well-tolerated in those with uncontrolled high BP.

One of the limitations of the study was that at least half of the subjects correctly guessed which allocation (Sham or Active) they were on at the end of the treatment (3 months), and that may have (in addition to the low number of study subjects) affected the results.

### **Conclusion – What the results means for patients with high blood pressure**

The study data show no safety concerns and good acceptability of the tAN device, suggesting that the device can be used in patients if proved to be effective at reducing BP. However, both groups recruited in this trial showed similar BP reductions. This means that based on the SCRATCH trial results, there will be no immediate change in the current treatment methods for patients with uncontrolled BP.

However, there are some suggestions from the data that the device treatment may show increased benefit in patients with more severe hypertension (systolic BP greater than 160mmHg). This data warrants further testing in future studies.