Title: Radial Artery Vasodilation Heat Study

NCT: NCT03620383

Date: 8/27/2019

Study Protocol:

Study subjects

Institutional review board (IRB) approval will be obtained for this prospective, randomized, single-blinded controlled clinical trial (NCT03620383). Study subjects will be recruited from among healthy healthcare workers with no currently active vascular or chronic disease. Exclusion criteria include prior history of left radial artery access. Study design and purpose were explained to the subjects prior to enrollment and written informed consent will be obtained.

Randomization

The census of the subjects will be enrolled in the study on a first-come-first-serve basis. The subjects will be randomized into palmar warming ("PaW") and control groups based on a draw from a pool of paper slips with a group assignment written on them. The draw will be conducted without replacement from a pool of 60 slips equally divided into heat and no heat groups. To avoid violation of randomization, the study is designed to stop when one group reaches to its maximum predicted number.

Blinding

The sonographer will be unaware of the group assignment of the subjects. Also, to prevent sensing the temperature of the palmar pad, the sonographer will hold the probe from its proximal-most point and avoided contact or proximity with the subjects' hand.

Intervention

The PaW group will be given a warm commercially available air-activated heat pack (Kobayashi Consumer Products LLC, Dalton, GA) to hold in the left hand for palmar warming. The control group will be given a de-activated version of the same heat pack to hold.

Radial artery cross-sectional area (CSA) measurement

Participants will be placed in a sitting position with their left forearm resting on a table. Before given the activated or de-activated heat pack, baseline left radial artery intraluminal height and width will be measured 2 cm proximal to the styloid process using an L20-5 linear array transducer with a ZS3 ultrasound system (Mindray Medical Systems, Inc, Mountain View, CA). A skin mark will be made at the site of measurement to ensure consistency in measurement location. The PaW group will then be given the activated heat pack and the control group will be given a de-activated heat pack. After 5 minutes of holding their respective heat packs, repeat left radial artery intraluminal height and width measurements will be obtained in both groups at the same location of the baseline measurement as indicated by the skin mark. Repeat height and width measurements will be again obtained after 10, 15, and 20-minutes of holding the assigned heat packs in both groups. Cross-sectional area (CSA) will be calculated according to the area for an ellipse based on height and width measurements. All sonographic measurements will performed by a single board-certified radiologist with two years of experience.