Assessment by Ultrasound of the degree of venous dilatation, comparison between venodilation by Airglove™ versus Warm Water Immersion (WWI)

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Title: Assessment by Ultrasound of the degree of venous dilatation, comparison between venodilation by Airglove™ versus Warm Water Immersion (WWI)

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Background Information:

Failure to cannulate to gain intra-venous access is a common occurrence in patients undergoing chemotherapy, obese patients, intravenous drug users and those with chronic medical problems leading to peripheral venous collapse. Difficulty in gaining IV-access is a serious medical consequence since important life-saving drugs, fluids, blood transfusions, and other medication are usually given via the intravenous route. Most chemotherapy units in the UK rely on venous dilation by immersing the forearm of patients with "difficult to cannulate veins" (DTCV) into a bucket of warm water. There are however, limitations in this method such as controlling water temperature and ensuring proper sterility.

A new device Airglove™ has been developed which directs warm air over the forearm in a polythene sleeve causing venodilation. Preliminary studies in chemotherapy patients suggest that the Airglove™ causes venodilation to the extent of the warm water immersion technique, however further evidence is required with testing on normal healthy volunteers.

Aims and Objectives:

To determine whether Airglove™ warming device dilates upper limb veins to the same degree as the warm water immersion (WWI) method.

Participants and Recruitment Methods:

Students and staff (n=30) from the School of Health and Life Sciences, who fit the inclusion/exclusion criteria, will be invited via email to take part in this non-invasive study. A participant information letter and consent form have been draw up to ensure appropriate informed consent is obtained. Details of gatekeeper access authorisation and a recruitment email are included with this application.

Inclusion Criteria:

* Participants > 18 years old
* Able to give written informed consent
* Able to understand and complete questionnaire forms independently

Exclusion Criteria:

* Participants < 18 years old
* Participants with cancer and/or undergoing chemotherapy
* Participants with difficult to cannulate veins (DTCV)
* Participants with lymphoedema in either hand
* Participants with pre-existing Raynaud's disease
* Participants with Diabetes (Type 1 & 2)
* Participants with generalised anxiety disorder
* Participants with diagnosis of hypertension
* Participants with any cardiovascular disease, previous stroke, episodes of DVT, recent treatment for venous thromboembolism (VTE), recently administered heparin, participants on warfarin or any anticoagulant treatment (including NOACs).
*Participants not able to give written informed consent
* Participants not able to comprehend or complete questionnaire forms independently

Design and Methods:

A prospective comparative study will take place in one of the ward areas of the Govan Mbeki Building, GCU Glasgow campus. Participants will expect to give up approximately 50 minutes to take part in the study. No payment or incentive will be offered.
Procedure:

- Anonymised participant demographic (age, gender, height, weight, body fat percentage, basal temperature and hydration status) data will be recorded electronically.
- Participants will be placed in a semi-recumbent position, while measurements are taken of the both arms. Blood pressure measurements will also be taken.
- Baseline 2D ultrasound long and short axis measurements of the dorsal metacarpal vein at the wrist and cephalic and median cubital veins of the cubital fossa will be taken.

Airglove™ Method Assessment:

- Select temperature setting at 38.5°C. Gently slide plastic sleeve onto RIGHT arm of volunteer, start machine. Airglove will warm the air for 3 minutes and will automatically stop.
- Discard the plastic sleeve and dispose of this as per GCU practice for recyclable plastics policy. (Sleeve is single use only).
- Carry our ultrasound examination of all 3 veins and record vein dimensions.
- Allow participants to rest 10 minutes before crossing to WWI method.

Warm Water Immersion Method Assessment:

- Collect warm water (from tap) into a bucket. Adjust the temperature of the water to 38.5° using titration of cold water
- Immerse entire RIGHT forearm of the volunteer into the bucket for 3 minutes. Remove arm and pat dry with appropriate towelling.
- Carry out ultrasound examination of all 3 veins and record the vein dimensions.

Repeat Airglove and warm water immersion procedures for participants LEFT arm.

Anonymised participant demographic data will be recorded and stored electronically and held as double password protected electronic file for analysis. Data will be confidential and anonymised at point of collection. Only the research team will have access to the data.
Anonymised ultrasound data will be recorded electronically within the equipment hard-ware – accessible via security system log in. Data will be transferred and held as double protected electronic file for analyses. Data will be confidential and anonymised at point of collection.
Electronic data will be stored securely at Glasgow Caledonian University for 7 years (end of project + 6 years in compliance with GCU Research Innovation and Enterprise record retention schedule, 2016).

Consent, confidentiality and anonymity: Participants will be provided with a participant information document to read prior to commencing the study. After coming into the study room participants have the opportunity to review the participant information document with a research team member and will have the opportunity to ask any questions or raise any concerns regarding their participation. Participation is entirely voluntary and participants may withdraw at any point. Following participant consent, participants will be allocated an ID number to ensure anonymity. Confidentiality will be maintained as only members of the research team will have access to the data with identifiable information. This data will be stored on a University owned and password protected computer. All data will be coded to ensure anonymity.

Risk to participants/self: There are no significant potential risks, psychological or physical, to participants foreseen in this study. Participants will be informed of all testing procedures beforehand and made aware of any potentially uncomfortable aspects. Light pressure will be applied to the skin surface of the forearm, however it is considered that there is no significant risk to participants.

Arrangements for debriefing: Following data collection, participants will be thanked for their participation and debriefed on the procedure completed. They will be given an opportunity to provide contact information if they wish to be informed of the results of the overall study and/or subsequent publications. Further, in the unlikely event that an unexpected finding occurs (e.g. detection of high blood pressure) the participant will be notified and results reported to the participants General Practitioner.

Statement of ethical considerations raised: All participants will be fully informed with consent prior to any data collection activities. No ethical considerations raised.