Nurse-led Placement of Peripheral Venous Catheters in Overweight Patients Using Standard or Dynamic Ultrasound-guided Technique (DUST)

NCT04412967

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Subject study information

Project title: ”Can ultrasound-guided peripheral venous cannulation reduce the number of cannulation attempts or shorten the time to a functional intravenous cannula in overweight patients in the emergency department?”.

We would like to ask you to participate in a study aiming to investigate if the use of ultrasound-technology can facilitate the placement of a peripheral venous catheter (PVC) in overweight patients.

Background:

Approximately 70 % of all patients who come to the emergency department receive a PVC. The PVC is typically used to administer medication. In dehydrated or overweight patients, more than one attempt to insert the PVC may be required. In the US, several studies in overweight patients have indicated that the use of ultrasound-technology may facilitate PVC insertion by decreasing the number of cannulation attempts and reduce the time required. In Sweden, no studies have been made to investigate if the use of ultrasound technology could have similar beneficial effects. The aim of this study is, therefore, to investigate if the use of ultrasound could facilitate the cannulation in overweight patients (BMI >25) at the emergency department. Specifically, the study aims to investigate if ultrasound-assisted cannulation results in fewer cannulation attempts and/or a decrease of time to venous access. We will also investigate if there are any differences in staff-reported, immediate adverse events, differences in patient-reported discomfort or differences in adverse effects that result in a re-visit within seven days and at a one month after cannulation.

Terms of participation

Your participation in this study is voluntary. You can, and at any point and without further explanation, choose to discontinue your participation. Your non-participation or discontinued participation in this study will not affect the emergency care provided. If considered necessary for medical or other reasons, your participation in the study may also be discontinued by a research nurse or a medical doctor. If you choose to discontinue your participation, please inform any person of the staff.

How is the study performed?

You will receive standard care, in accordance current guidelines whether you choose to participate or not. If you choose to participate, you will be randomly assigned to receive a PVC either by ultrasound-guided technique or by standard technique. We will also ask how you perceived the procedure and check your medical records at seven days and one month for any information about adverse events.

Potential risks and side effects:

Insertion of peripheral venous catheters is always associated with some level of risks. The study procedure is not expected to generate any increased risk compared to the risks associated with standard care procedure for PVC insertion in an emergency department setting. The risks associated with the standard procedure for insertion of PVCs are well known as PVCs have been used since the 1950s. The most commonly reported side effect is discomfort (pain or a burning sensation) as the skin is penetrated. Other risks are infection, the formation of blood clots or damage to vessels or nerves. There are no additional risks reported for ultrasound-guided cannulation compared to standard technique. Instead, ultrasound-guided cannulation could decrease the risk for misplacement or damages since it provides guidance by visual identification of nerves and vessels.

Staff working in this study have received training in ultrasound-guided cannulation in a clinical setting.

There are no obvious personal advantages for you as a patient to participate in this study. However, if the ultrasound-guided cannulation method turn out to be effective in terms of fewer attempts and shorter time needed to insert a functional PVC, it could be of benefit to future patient.

Insurance:

If you choose to participate in this study, you are entitled to the same insurance protection as all other patients within the healthcare system (as stated by the Patient Injury Act and The Swedish Pharmaceutical Insurance). If you suffer an injury while in the healthcare system, you may in some cases be entitled to financial compensation under the Patient Injury Act. The Swedish Pharmaceutical Insurance covers any adverse reactions or side effects due to the administration of medications.

If you believe that you have suffered an injury due to your participation in this study, please report this to: Akutkliniken, Universitetssjukhuset, Linköping.

Management of personal data:

Data concerning your medical condition will be recorded in your medical records according to standard procedure. In addition, any information concerning the study will be recorded in separate study records. By providing your consent to participate, you agree to the collection, analysis and presentation of study data for research purposes. If you choose to discontinue your participation you may have your data removed from the study.

All data collected in this study are stored, analyzed and presented in accordance with the regulations of Region Östergötland and Linköping Universitet. The results will be published in scientific journals and data will be presented at a group level without the possibility to identify any individual participants.

If requested, you may receive a transcript of your data and information about the results of the study.

Economic compensation:

There will be no economic compensation for participation in this study.

Informed consent form

I hereby consent to participate in the study (circle an option) Yes No

_____ _____

Participant's signature Date (YYYY-MM-DD), location

_____ _____

Person who obtained the informed consent Date (YYYY-MM-DD), location

(Nurse or Medical Doctor)

Contact information:

Principal investigator:

M.D., Ass. Prof. Daniel Wilhelms

daniel.wilhelms@regionostergotland.se

010 – 10 30 000 (switchboard).

Study nurse:

Research nurse, Joakim Glasin,

joakim.glasin@regionostergotland.se

For emergencies, please contact Akutkliniken, Universitetssjukhuset i Linköping, for 24 hrs service.