Title

Piloting new patient centric sampling approaches in phase-1 clinical trials

Introduction

Patient centric sampling (PCS) devices can offer a lot of benefits, such as collection of blood samples from patients in 'remote' or difficult to reach areas, frail patient populations, e.g., paediatrics, elderly, etc. By facilitating trial participation for disabled subjects, or those with limited access to healthcare, PCS can also enhance clinical trial diversity. Although PCS is becoming more mature, challenges such as comparability to traditional venous blood sampling remain.

Method and Materials

We used two different PCS devices in two different phase-1 clinical trials with Normal Healthy Volunteers (NHV). A first trial compared the concentrations of compound X obtained from traditional venous plasma (venipuncture) with those in venous whole blood and capillary whole blood (finger stick) collected with the Mitra Cartridge at the same timepoints. Another study compared the pharmacokinetics of compound Y in venous plasma with those in capillary whole blood samples collected with the Tasso-M20 device at the same timepoints.We used two different PCS devices in two different phase-1 clinical trials with Normal Healthy Volunteers (NHV). A first trial compared the concentrations of compound X obtained from traditional venous plasma (venipuncture) with those in venous whole blood and capillary whole blood (finger stick) collected with the Mitra Cartridge at the same timepoints. Another study compared the pharmacokinetics of compound Y in venous plasma with those in capillary whole blood samples collected with the Tasso-M20 device at the same timepoints.

Results

The blood-to-plasma ratio of compound X was found to be constant over the observed concentration range. Applying a correlation factor of 1.622, the concordance correlation between plasma concentrations predicted from capillary blood (Mitra Cartridge) and the actual concentrations measured in plasma (venipuncture) was 0.978 (95% CI: 0.970 – 0.984).

For compound Y, venous plasma (venipuncture) and matching capillary samples (Tasso-M20) were compared and showed similar shapes of the concentration-time profiles for venous plasma and capillary whole blood. The geometric mean (90% CI) compound Y Cmax and AUCinf for capillary whole blood versus venous plasma were 91% (85%-98%) and 84% (82%-87%), respectively.

For Tasso-M20, general feedback on the device's use was obtained from the participants and site personnel. Most participants felt comfortable enough to use the device by themselves at home. Almost 80% of the trial nurses preferred the Tasso-M20 over venipuncture.

Conclusion

For the Mitra Cartridge the PK results show a good correlation between venous and capillary concentrations of compound X. The PK results of the Tasso-M20 device demonstrate a small difference between venous and capillary concentrations during the distribution phase of compound Y, resulting in a more difficult implementation of the device for compound Y.

Both results prove the potential and pitfalls of PCS and the need for case-by-case assessments and bridging studies.

Although PCS devices require extra training of staff/patients to ensure devices are used correctly to collect the required blood volume, both participants and nurses felt comfortable while using the Tasso-M20.

Authors

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