EVALUATION OF THE REAL-WORLD PHARMACOKINETICS OF LONG ACTING RILPIVIRINE/CABOTEGRAVIR FOR TREATMENT OF HIV INFECTION – THE JABS PKinSITE STUDY

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Background:
There is increasing uptake of long-acting (LA) Cabotegravir and Rilpivirine for treatment of HIV infection. Royal Perth Hospital has successfully implemented LA therapy in over 170 people living with HIV. While virological failure is rare, the observed pharmacokinetic inter-individual variability around 2 monthly fixed dose injections raises a possible issue of subtherapeutic antiretroviral concentrations and its associated consequences in more diverse "real world" populations. Further, subcutaneous (SC) exposure during intramuscular (IM) injections is not uncommon and could contribute to variability in drug exposure.
We undertook a pharmacokinetic study to explore (i) how local injection site factors may influence inter-individual variability, and (ii) the potential role of therapeutic drug monitoring.

Methods:
A validated assay for LA Cabotegravir and Rilpivirine concentrations was developed and outpatients currently receiving these agents were recruited to the study. Over a 16-week period additional blood monitoring to measure drug concentrations and an ultrasound scan following injections to assess subcutaneous tissue thickness (SCT) and injection site, were performed.

Results:
Between October 2023 and March 2024, 31 patients were recruited, with data collection to be completed in mid-July 2024. This will provide information on real-world inter-individual variability in pharmacokinetics alongside a novel exploration on the potential impact of SCT and injection site. Our interim results show SCT correlating with site (mean; 14.5mm IM vs 37.5mm SC) and gender (mean; male 19.3mm, female 30.4mm). Overall up to 40% (40/100) of injections had some subcutaneous exposure correlating with increasing SCT however there were no cases of virological failure.

Conclusion:
We expect to describe real world drug concentrations and variability within a pharmacokinetic model in our cohort, with a focus on the potential impact of injection site variables. This data will add to existing literature to help better understand the potential value of therapeutic drug monitoring.

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