A Novel Measurement Method to Determine Patient Adherence to PCSK9 Inhibitor Treatment

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PCSK9 inhibitors are a new class of cholesterol-lowering drugs that are complicated to take: patients have to inject themselves every 2 weeks and store the medicine in the refrigerator between 2-8 C to keep it from spoiling. The primary research question for the study was: Do patients have problems adhering to the prescribed implementation protocol for PCSK9 drugs? The study was designed to quantitatively track patient drug dosing histories with placebo over a 4 week period using an electronic logger that recorded temperature storage of the medicine package and an electronic cap that recorded the date/time of placebo syringe disposal Results showed: • 47% of subjects experienced an excursion above or below 2-8 C for > 24 hours • 53% of subjects did not perform the warming process (most missed at both opportunities) • 32% of subjects exceeded the 14 day (+/- 1 day) dose interval tolerance • Temperature excursions varied by storage location within the refrigerator • 30% of hand recorded patient diary entries did not match the passively measured date/times electronically recorded The measurement technique used in the study quantitatively showed that the PCSK9 protocol appears to be difficult to implement. Additionally, one cannot assume that a home refrigerator will keep medicine stored at the recommended temperature range of 2°C - 8°C. With this level of detailed information, the healthcare system can better train patients to ensure they take PCSK9 medicines correctly. Most importantly, the healthcare system can reduce the risk that the investment in a much more expensive therapy (compared to statins) is not wasted due to poor temperature conditions and poor execution of the dosing protocol.

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