Woodley Trial Solutions delivers continuous glucose monitoring support to clinical trial

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Clinical trial	**This trial is a randomized, open-label study comparing the efficacy and safety of inhaled insulin with rapid-acting insulin analog injections. Both cohorts of type 1 and type 2 diabetic pediatric participants are also being administered with slow-acting basal insulin**
Total number of patients	264
Global sites	60 across the US
Robust supply chain	Prompt delivery of equipment amid the COVID-19 pandemic
Minimized downtime	Coordinated and timely CGM device delivery – both initial and resupply - to eliminate the potential for downtime

The nature of diabetes means that the condition is almost never static, often requiring constant monitoring and treatment. Traditionally this would require one or more finger pricks per day to determine blood glucose concentrations, with the administration of insulin injections to return levels to a healthy baseline where required.[1] However, there have been several innovations in recent years geared towards moving diabetes management away from this needle-based model, such as point-of-care continuous glucose monitoring (CGM) and powdered, inhaled insulin. An ongoing study has incorporated two such developments and, with continued support from Woodley Trial Solutions, seeks to determine the effectiveness of inhaled insulin for children with diabetes.

The study

The trial is a randomized, open-label study comparing the efficacy and safety of inhaled insulin with an injected rapid-acting insulin analog, in pediatric subjects with type 1 or type 2 diabetic mellitus. Each participant is also being administered a slow-acting basal insulin. The trial is being conducted across 60 US sites, with enrollment of 264 participants, and is using CGM systems – supplied and managed by Woodley Trial Solutions – to provide continuous monitoring of blood glucose levels.

Proactive patient treatment using CGM

The monitoring system chosen for the trial includes a discrete, wearable monitor that tracks blood glucose levels via a sensor placed just below the skin. The benefits of this approach are two-fold. Firstly, it eliminates the finger pricks associated with diabetes management, which can often be a cause of discomfort and anxiety for newly diagnosed patients. Secondly, it collects a continuous stream of data over an extended period of time, which can be used to determine real-time trends in blood glucose levels, allowing patients to take proactive action before any serious issues can arise. This contrasts with the sporadic nature of blood glucose testing via a finger prick, where an issue is often only picked up once glucose levels have already drifted outside of the desired range. A major benefit of CGM in a clinical trial setting is that data can be automatically and remotely uploaded to a central location and reviewed and monitored by the clinical trial medical personnel, simplifying the execution of the study.

Steady supply

The supply of equipment to clinical trials spread over multiple sites can be demanding, even in the most stable of conditions. But logistical challenges caused by fluctuating COVID-19 policies have demanded an extra level of flexibility from Woodley Trial Solutions, which has relied on its extensive experience of supplying equipment to clinical studies. The company's renowned attention to detail and constant communication with the trial sponsors and contract research organization has ensured a consistent supply of equipment throughout the trial. This is especially crucial in the case of the blood glucose monitors, since the sensors and transmitters need regularly replacing after 10 and 90 days of use, respectively. Additionally,

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all stock is closely monitored and managed using an inventory tracking system, minimizing delays due to equipment oversights. Woodley Trial Solutions' support is ongoing, and will continue until the trial is completed in April 2023.

Summary

The study intends to recruit more participants over the next year in order to collect as much data as possible, and Woodley Trial Solutions' supply model will comfortably scale up to accommodate the demands of this expansion. The company places a great deal of value on relationships, and it is the close partnerships and effective communication with both the trial sponsors and the contract research organization that has allowed the steady and timely supply of blood glucose monitors to the study, ensuring no downtime due to equipment oversights. Hopefully the success of this and similar trials will further promote the benefits of CGM in diabetes management, and help to improve diabetic patients' quality of life.

The trial is being conducted across 60 US sites, with enrollment of 264 participants, and is using CGM systems – supplied and managed by Woodley Trial Solutions.

References

1. US Centers for Disease Control and Prevention, *Just diagnosed with type-1 diabetes*

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