ALTASCIENCES

CASE STUDY

FIH Clinical Trial Involving QT Assessment

STUDY OVERVIEW

Altasciences recently conducted a FIH clinical trial involving QT assessment on a novel cannabis formulation, the results of which are presented below:

A Double-Blind Phase I Study to Assess Safety, Tolerability, Pharmacodynamics and Pharmacokinetics of Single and Multiple Daily Ascending Doses of Cannabis (Delta-9-tetrahydrocannabinol/Cannabidiol) in Healthy Male and Female Volunteers/Fasting State

This was a single center, double-blind, placebo-controlled, randomized-within-dose, single-and multiple-dose escalating study. The study included 80 subjects evaluated in 2 parts — Part A (single-ascending dose) and Part B (multiple dose) in healthy volunteers.

ALTASCIENCES' APPROACH

Altasciences recently conducted a FIH clinical trial involving QT assessment on a novel cannabis formulation, the results of which are presented below:

A Double-Blind Phase I Study to Assess Safety, Tolerability, Pharmacodynamics and Pharmacokinetics of Single and Multiple Daily Ascending Doses of Cannabis (Delta-9-tetrahydrocannabinol/Cannabidiol) in Healthy Male and Female Volunteers/Fasting State

This was a single center, double-blind, placebo-controlled, randomized-within-dose, single-and multiple-dose escalating study. The study included 80 subjects evaluated in 2 parts — Part A (single-ascending dose) and Part B (multiple dose) in healthy volunteers.

A cardiodynamic ECG assessment was conducted in Part B of the study to evaluate the effects of a novel cannabis formulation on the corrected QT interval (QTc) using Fridericia's formula (QTcF). Because the QT interval is directly dependent on the heart rate in an obvious way, (i.e., a faster heart rate produces a shorter R–R and QT interval), the collected data is adjusted accordingly for accuracy and to improve arrhythmia detection.

QTc evaluation was conducted following cannabis administration over 1 and 7 consecutive days in an escalation fashion to healthy male and female subjects.

Three different multiple-dose groups (1x, 2x, and 3x daily dosing) were evaluated. Altasciences worked with ERT as our central ECG laboratory to help extract and analyze the ECGs.

Ten 14-second digital, 12-lead ECG tracings were extracted from a Holter monitor, using the 'TQT Plus method', at protocol-specified timepoints. This method enabled extraction of ECGs through continuous cardiodynamic recordings while minimizing HR variability and noise. High-precision QT analysis was subsequently performed on all analyzable beats in the 10 ECG replicates.

In all dose groups evaluated for this cannabis formulation, it was determined that the change from baseline QTcF was small and that although a shortening of the PR interval was observed, there was no clinically meaningful effect on the QRS interval.

THE OUTCOME

In all dose groups evaluated for this cannabis formulation, it was determined that the change from baseline QTcF was small and that although a shortening of the PR interval was observed, there was no clinically meaningful effect on the QRS interval.

ABOUT ALTASCIENCES

Altasciences is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. For over 30 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.

© 2020 Altasciences. All Rights Reserved.