

CASE STUDY

Advancing Innovation

Prescreening and Safety Simplify Complex Vaccine Study

Study Description

A randomized, double-blind, placebo-controlled, multidose escalation, safety, tolerability, and immunogenicity study

Study Objective

To determine the safety and tolerability of four dose combinations of the study drug

Study Compound

Vaccine

Patient Population

Patients with mild-to-moderate Alzheimer's disease

Treatment Period

Sixty-five weeks

Primary Efficacy Parameter

Safety phase dose finding

Participating Countries

United Kingdom

Study Specifics

- > Active sites: 4
- > Patients randomized: 80 (target)
- > Recruitment period: 5 months
- > Recruitment dates:
March – August 2000

Quintiles Services

Project Management, Clinical Monitoring, Pharmacovigilance, Central Laboratories, Clinical Trial Supplies

Overview

This was a complex Phase-II study with interim analyses over a 7-month period as well as implementation of several rating scales. Quintiles' advance planning and training enabled investigators to screen patients before study start-up and achieve a very low screen failure rate. Due to successful motivation and coordination at the sites, all safety and interim analyses were carried out within the timelines requested by the customer.

Key Challenges

- > *Eighty patients had to be enrolled in 4 groups of 20 patients, with 16 patients in each group receiving a placebo.*
- > *Groups B and C could be enrolled only after the safety data from group A had been assessed, and group D could be enrolled only after the data from groups B and C had been assessed. The customer and an independent Drug Safety Monitoring Board assessed the interim data.*
- > *All 80 patients had to be identified and screened at the outset of the study. Because each patient would receive 4 injections over 24 weeks and would be followed for a total of 65 weeks, patients and caregivers would have to visit the investigator a total of 18 times.*
- > *The study required blinding of both the investigators and the CRAs.*

How Were These Challenges Met?

- > *Before starting the study, Quintiles met with the client to clarify all issues pertaining to the complex protocol.*
- > *Quintiles also met with all CRAs and study site coordinators and provided an independent psychologist to instruct them on the disease and the rating scales. This training enabled study site coordinators to search the investigator databases and provide a list of suitable patients for all sites.*

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- > *Study site coordinators managed all appointments and maintained contact with patients and caregivers to ensure that they kept their appointments.*
- > *Quintiles provided planning materials for each site and helped investigators manage the study.*
- > *To maintain the blind parameter of the study protocol, Quintiles established a Pharmacy Monitoring Team to manage drug accountability, dispensing and administration.*

Outcome

All 80 patients were ready to enter the study within recruitment timelines and successfully followed up for the 65 weeks.

Contact Us:

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