

Study Description

Phase III, randomized, multicenter, open-label study of a novel chemotherapy + cisplatin.

Study Objective

Evaluate the efficacy of a novel chemotherapy+cisplatin with that of 5-fluorouracil (5-FU)+cisplatin on survival in advanced gastric cancer patients.

Study Compound

A novel oral fluorouracil combination

Patient Population

Patients with advanced gastric cancer without prior chemotherapy

Treatment Period

The novel chemotherapy+cisplatin or 5-FU+cisplatin was administered (6 cycles) followed by the novel chemotherapy or 5-FU alone (every 4 weeks) until intolerable side effects, progressive disease, withdrawal of consent, or death occurred. Patients were then followed every 2 months for up to 5 years.

Primary Efficacy Parameter

Overall survival

Participating Countries

25 - Argentina, Australia, Belgium, Brazil, Canada, Chile, Columbia, Croatia, Czech Republic, Estonia, France, Germany, United Kingdom, Hungary, Italy, Mexico, Netherlands, Peru, Poland, Portugal, Russia, South Africa, Spain, Ukraine, United States

Study Specifics

- Number of active sites: 188
- Patients randomized: 1,053
- Recruitment period: 22 months
- Recruitment dates: May 2005 to March 2007

Quintiles Services

Project Management, Clinical Monitoring, Regulatory, Pharmacovigilance, IVRS

Key Challenges

Several factors posed a challenge for patient recruitment: the small target patient population for gastric cancer, the study requirement that targeted patients be in good physical condition despite having advanced gastric cancer, and complicated primary-tumor-related inclusion criteria that oncologists found difficult to interpret.

The large, multinational nature of the trial, which involved diverse, country-specific regulatory guidelines and required management across multiple time zones presented complications for study start-up.

A large number of patients and the dense, technical nature of the data records added complexity to the data review.

How Were These Challenges Met?

To meet the challenges in patient recruitment, Quintiles relied on its therapeutic experience and extensive global site network to select the study sites most likely to treat patients meeting study entry criteria. In order to assist oncologists in working with the primary-tumor-related inclusion criteria, CRAs provided training to all sites based on a radiological briefing document.

To ensure a smooth study start-up, Quintiles provided a dedicated regulatory lead to work with local experts in each of the participating countries, assigned study site coordinators to key sites and as-needed expert consultation to all study sites, monitored each site to ensure that it had the appropriate resources, and held frequent face-to-face meetings to coordinate with the project management teams, CRAs, and vendors.

CTLs and CRAs with medical degrees participated in the medical review of the case report forms to facilitate data clean-up for a timely database lock.

Outcome

Recruitment and study start-up goals were met with an average recruitment rate of 0.34 patients per site per month. Quintiles substantially exceeded the original recruitment target (Figure) by enrolling 700 patients 9 months early to allow a 50% increase in sample size within the original study timelines. Data clean-up was also achieved in record time.

