Rescue of an Ongoing Global, Multi-Site Oncology Trial

BACKGROUND

Year(s): 2008 - ongoing
Lead Site: National Cancer Centre Singapore (NCCS)
Therapeutic Area: Oncology
Indication: Dukes C and high-risk Dukes B colorectal cancers
Intervention: Aspirin (200 mg)
Phase(s): III

The NCCS, an oncology center for research, education, and clinical services, is leading an international, multi-center, double-blind, randomized, placebo-controlled Phase III trial to determine the potential role of aspirin as an adjuvant agent in patients with established colorectal cancer. Eligible, consenting patients with Dukes C colon cancer, high risk Dukes B colon cancer, Dukes B rectal cancer, or Dukes C rectal cancer who have undergone resection of the primary tumor and completed standard treatment (chemotherapy ± radiotherapy) are randomized to receive aspirin or placebo for three years.

CHALLENGE

Many challenges have been faced since study initiation, including poor patient compliance and high drop-out rates due to the long intervention and follow-up duration; slow enrollment and poor patient retention in China; and insufficient staff.

Following the first patient in (FPI) in 2012, enrollment was 10% of the monthly enrollment target. As of January 2013, only 261 patients had been randomized (of the estimated sample size of 1200 patients). With the existing CRO relationship, challenges included a lack of manpower and no local CRO office in China. Instead, CRO activities, including monitoring, were conducted by CRAs who periodically flew to China. Therefore, in 2013, NCCS began searching for a new CRO partner to help monitor sites located external to Singapore, specifically those in China.
The study is expected to recruit the last patient by the end of 2020, with the last patient potentially being followed until 2025. As of April 2019, a total of 1,355 patients had been randomized, with a retention rate of 70%. Enrollment rates have been steadily increasing, with the highest enrollment rates at the sites in China.

The lead site has been pleased with FHI Clinical’s willingness to collaborate, proactive proposals to solve issues, and flexibility for billing and expenses. FHI Clinical has remained committed to the success of the trial, helping to solve recurring challenges with the enrollment rates, most recently through patient education about the study and study objectives. The lead site has indicated that they will continue to work with FHI Clinical on future studies, particularly when the studies involve sites in China.

SOLUTION

NCCS selected the FHI Clinical team as the new CRO partner based on a recommendation from the Project Manager at NCCS who had previously worked with FHI Clinical’s South East Asia Infectious Disease Clinical Research Network (SEAICRN) and was familiar with FHI Clinical’s ability to meet deliverables.

To address patient enrollment, FHI Clinical proposed adding four additional sites. These sites were quickly brought into the trial group. After budget and resource allocation, three of these sites were selected. Site start-up went smoothly, and patients were rapidly enrolled into the study.

When an administrative amendment for consent was required, the study risked losing existing patients or missed clinic visits. FHI Clinical proposed gaining verbal consent over the phone, followed by the patient signing and mailing a hard copy.

To support increased patient enrollment, the lead site delegated FHI Clinical in November 2015 to arrange the sites’ administrative services to avoid data backlog and incomplete forms. This arrangement is continuing until the end of the study contract.

To conserve budget around a needed investigators’ meeting in China, FHI Clinical made use of an oncology meeting that was also being held in March 2019 in southern China, where most of the study sites are located. FHI Clinical worked with the hospital organizing the meeting to offer a discount to the study personnel and to extend the meeting for the investigators’ meeting. As a result, the meeting was held at that time, and accommodation was funded by the lead site.

RESULTS

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