Implementation of an Osteoporosis Research Program with a Mobile Dual-Energy X-Ray Absorptiometry Unit: The Montana/Wyoming Experience

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Abstract. To expedite recruitment, and subject participation, for a large clinical osteoporosis therapy trial utilizing the bisphosphonate ibandronate, an integrated network of 13 satellite clinical sites was developed, linked by a mobile clinic vehicle transporting a dual-energy X-ray absorptiometry (DXA) unit. A predominantly rural area of the United States (Montana, northern Wyoming) was accessed for the project, due to the large pool of potential subjects living in this area who were not yet involved in osteoporosis clinical studies. The results of the project to date (through 10 months) confirm the feasibility of such a study design, with 1774 subjects screened by DXA for the study, and 280 (15.8%) accepted. The mobile DXA unit has functioned according to specifications for a stationary DXA machine, with the stability of spine phantom measurements over 10 months assessed as a coefficient of variation of 0.46%. The success of the project validates the concept of performing clinical osteoporosis therapy trials in previously underutilized rural community settings, facilitated by a satellite site network and mobile clinic.

Keywords: Bisphosphonates; Dual-energy X-ray absorptiometry; Ibandronate; Osteoporosis; Rural clinical research

Introduction

Osteoporosis is a common and expensive disease [1,2] with numerous therapies currently or recently under evaluation [3–5]. The majority of clinical therapy trials are conducted in well-populated urban communities in proximity to large academic institutions with access to advanced technologies and experienced clinical investigators. However, large areas of the United States are not involved in such studies due to the lack of availability of required study technologies, and to the lack of familiarity with the intricacies of clinical trial participation on the part of prospective study populations and practitioners.

The Northern Rocky Mountain area of the United States that contains the State of Montana and the northern portion of Wyoming has over 320000 women age 18 years or older with 39% of these over the age of 40 years. The presence of a relatively homogeneous female population of Northern European extraction coupled with a high prevalence of osteoporosis makes this region attractive for osteoporosis treatment studies [6]. However, this is an area of approximately 171500 square miles (444500 km²) with a population of about 946000. This is an average of about 5 persons per square mile or the equivalent of Manhattan Island with 135 residents. Based on population density, 84% of the counties in this region are classified as American Frontier and most of the remainder are classified as rural, having more than 6 but fewer than 100 residents per square mile. These demographic features make it very difficult to conduct a large clinical trial for osteoporosis using standard approaches.
We therefore planned a clinical osteoporosis therapy trial utilizing a mobile dual-energy X-ray absorptiometry (DXA) unit and an integrated network of satellite sites with dedicated on-site co-investigators. Such an innovative concept would address the problem of recruiting subjects and implementing such a study in a sparsely populated, large geographical region that does not have access to DXA technology. In addition, the availability of a mobile unit would overcome the reluctance of older female volunteers to leave their community to participate in a clinical trial. This report reviews the logistics, results and efficiency of this concept in meeting study goals.

Patients and Methods

This project originated as part of a world-wide clinical trial assessing the efficacy of a new bisphosphonate—ibandronate (BM 21-0955, Boehringer Mannheim GmbH, Mannheim, Germany) – in the treatment of osteoporosis. This ongoing prospective, randomized, double-masked, placebo-controlled 3-year study is designed to assess the efficacy and safety of ibandronate administered intravenously every 3 months to postmenopausal women aged 55–75 years with established (vertebral compression fractures) osteoporosis. During the 3-year study, subjects undergo spine radiographs yearly, bone mineral density (BMD) measurement with DXA every 6 months, and blood and urine tests for safety and the delineation of the mechanism of drug action every 3 months. The trial is conducted at 27 sites in the United States including the Deaconess Research Institute (DRI), Billings, Montana, and the University of Washington, Seattle, Washington.

Organizational Structure

Twenty-four hundred women are to be recruited worldwide, with DRI responsible for 300–400 of these from Montana and northern Wyoming. Facilitating this recruitment in Montana/Wyoming is a plan developed to utilize DRI as the central coordinating site (CCS) with 13 satellite sites linked by a mobile laboratory equipped with a Hologic 4500 DXA machine providing BMD and radiographic morphometry (MXA). The University of Washington Osteoporosis Research Group provides technical advice and collaboration in the overall clinical research aspects of the Montana/Wyoming project.

Figure 1 denotes the catchment area for the Montana/Wyoming project. The average population of the 13 sites is approximately 15000 persons (range: Great Falls, Montana 66000; Dillon, Montana 5000). The average distance of the 13 sites from the CCS (Billings, Montana, population 95000) is 180 miles (290 km). Each satellite site consists of a physician co-investigator and a quarter-time registered nurse (RN) or nurse practitioner (NP) (Fig. 2). The co-investigator is a local primary care practitioner, recruited via state medical societies and subsequent interview, with interest in clinical research, strong ties and reputation in the local medical community, and some knowledge of the medical management of osteoporosis as well as of bone density measurements with DXA. The responsibilities for the co-investigator include knowledge of the protocol and overall study project with a commitment to subsequently disseminate this information to the local medical community, recruitment of prospective study subjects, interaction with the local media to increase project visibility (as coordinated by the study’s public relations firm), and provision of medical advice during the study. Patient management in the study is the primary responsibility of the RN/NP, including coordination of drug administration every 3 months, and data retrieval/data recording.