

A randomized double-blind placebo-controlled study to evaluate the efficacy and safety of Cinacalcet for the treatment of Hypercalcemia in subjects with primary hyperparathyroidism unable to undergo Parathyroidectomy

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Purpose of the study: This phase 3, randomized, double-blind, placebo-controlled study is designed to demonstrate the efficacy and to assess the safety of cinacalcet for the reduction of hypercalcemia in subjects with primary HPT for whom parathyroidectomy is indicated on the basis of an elevated corrected total serum calcium, but who are unable to undergo parathyroidectomy. The reasons a subject would be unable to undergo parathyroidectomy include failed parathyroidectomy, medical contraindication to surgery, or because together with their primary physician they decided it was inappropriate. The study will consist of a 30-day screening phase, a 12-week placebo-controlled dose-titration phase, and a 16 week placebo-controlled efficacy assessment phase (EAP). Subjects who complete 28 weeks on study will continue into an open-label safety extension phase for 24 weeks of investigational Cinacalcet treatment.

Biography

Aliya Khan is a Professor of Clinical Medicine, Divisions of Endocrinology and Geriatrics McMaster University and Director of the Calcium Disorders Clinic at St. Joseph's Healthcare, McMaster University She has published over 100 scientific papers on osteoporosis and parathyroid disease. She is the Editor of the Handbook of Parathyroid Diseases. She co-chaired the 3rd International Consensus Conference on Primary Hyperparathyroidism and the 1st International Workshop on Hypoparathyroidism. She is the founding Chair of the ISCD Canadian Panel and the past Chair of the ISCD Certification Council. She has been recognized by national and international awards including the International Clinician Instructor of the Year 2011 award by the ISCD as well as the Queen's Diamond Jubilee Medal for 2012 for excellence in clinical care, research and teaching.

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