ForPatients

by Roche

Breast Cancer HER-2 Positive

A Safety and Tolerability Study of Assisted and Self-Administered Subcutaneous (SC) Herceptin (Trastuzumab) as Adjuvant Therapy in Early Human Epidermal Growth Factor Receptor 2 (HER2)-Positive Breast Cancer

Trial Status Trial Runs In Trial Identifier

Completed 59 Countries NCT01566721 2011-005328-17

MO28048

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This multicenter, two-cohort, non-randomized, open-label study will evaluate the safety and tolerability of assisted and self-administered SC Herceptin as adjuvant therapy in participants with early HER2-positive breast cancer following tumor excision. Participants will receive Herceptin 600 milligrams (mg) SC every 3 weeks for 18 cycles, either by an assisted administration using a conventional syringe and needle/vial formulation (Cohort A) or with assisted and self-administration using a single-use injection device (SID) in selected participants (Cohort B).

Hoffmann-La Roche Sponsor		Phase 3 Phase	
NCT01566721 2011-005328-17 MO28048 Trial Identifiers			
Eligibility Criter	ia:		
Gender All	Age >=18 Years	Healthy Volunteers No	