# Title Page

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| **Title** | "A Prospective, Multicenter, Six-Month Study on the Effectiveness, Safety and Impact on Health Related Quality of Life (HRQoL) and Depression Symptoms of Paricalcitol administered to Venezuelan Patients with Chronic Kidney Disease (Stage V) who are on Hemodialysis" |
| **Protocol Version Identifier** | P13-785 Version 1.0 (05 October 2012) |
| **Date of Last Version of Protocol** | 05 October 2012 |
| **EU PAS Register Number** | Not applicable (ClinicalTrials.gov identifier: NCT01758289) |
| **Active Substance** | Paricalcitol IV |
| **Medicinal Product** | Zemplar IV® |
| **Product Reference** | ABT-358 |
| **Procedure Number** | N/A |
| **Marketing Authorization Holder(s)** | Abbott Laboratories S.A. [redacted] |
| **Joint PASS** | No |
| **Research Question and Objectives** | This study was designed to evaluate the effectiveness, safety; impact on quality of life related to health and depressive symptoms when Paricalcitol is administered in Venezuelan patients on hemodialysis, and who are on risk to develop secondary hyperparathyroidism associated, with stage V chronic kidney disease.<br>**Primary objective:**<br>This study was designed to evaluate the effectiveness of Paricalcitol administered in Venezuelan patients with stage V renal disease on hemodialysis. Effectiveness is measured by evaluating the proportion of patients achieving at least a 30% reduction in the PTH from baseline compared with values in the final study visit. |
| **Country(-ies) of Study** | Venezuela, mono-country study |
| **Author(s)** | [redacted] |