

PROCRIT[®] Dosing at Q2W vs. QW in Anemic HIV Subjects

Ortho-BioTech Protocol PRO4-29-007: A Randomized, Open Label Study Assessing the Efficacy of Initiating PROCRIT[®] Dosing at Q2W vs. Initiating PROCRIT[®] Dosing at QW in Anemic HIV-Infected Subjects

Purpose: To determine if PROCRIT[®] initiated at every other week (Q2W) dosing is as effective as weekly initiation (QW) dosing in increasing hemoglobin in anemic (<12.0g/dL) HIV-infected subjects.

About the study: This is a two-arm, randomized, open label, multi-center study. The screening phase will start 2 weeks prior to the first dose of PROCRIT[®] (baseline/Day 1). HIV-infected subjects who have a hemoglobin of <12.0g/dL and are on a stable anti-retroviral treatment (ART) regimen will be screened for study eligibility. All qualified subjects will enter the treatment phase. Subjects who have satisfied all eligibility criteria will be randomly assigned in a 1:1 ratio to receive PROCRIT[®] QW 40,000 U SC injections or Q2W 40,000 U SC injections. Hemoglobin levels will be taken weekly on all subjects during the treatment phase of the study. The total duration of this study is 14 weeks, including a 2-week screening phase and a 12-week treatment phase.

Required:

- Female subjects must have a negative urine pregnancy test at screening and be postmenopausal, surgically sterile, or practicing an effective method of birth control
- Subjects must be documented HIV+ and on a stable antiretroviral regimen for at least 4 weeks prior to enrollment
- Hemoglobin <12.0g/dL
- No active cancer or cancer therapy within 12 months prior to enrollment

Not Allowed:

- History of acute, symptomatic opportunistic infection or other acute AIDS defining illness within 6 months of enrollment
- History of any primary hematologic disease
- Anemia attributable to factors other than HIV infection (i.e. iron, B₁₂, hemolysis or G.I. bleeding)
- HCV co-infected subjects (documented HCV-RNA test within 30 days prior to Baseline Visit)
- Uncontrolled or severe cardiovascular disease including recent (6 months) myocardial infarction

Study Location:

Orange County Center for Special Immunology
11190 Warner Avenue, Suite 411
Fountain Valley, CA 92708
Tel: 714-751-5800/Fax: 714-751-5860
Contact our Research Dept. at ext. 26