عنوان مقاله:

Efficacy and Safety Non-Inferiority Comparison of Biosimilar Bevacizumab (Stivant®) to the Reference Product (Avastin®) in Patients with Prethreshold Type I Retinopathy of Prematurity

محل انتشار:

بیست و نهمین کنگره سالیانه انجمن چشم پزشکی ایران (سال: 1398)

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خلاصه مقاله:

Purpose: This study aimed to compare efficacy and safety of Bevacizumab (Stivant®, CinnaGen, Iran) to the innovator product (Avastin®, Genetech, South San Francisco, CA) in premature infants with prethreshold type I retinopathy of prematurity (ROP). Methods: In a non-inferiority case series, contralateral eye study preterm infants with bilateral type 1 ROP (zone I ROP, any stage with plus disease or zone I ROP, stage 3 without plus disease or zone 2 ROP stage 2 or 3 with plus disease) were enrolled in this. Under topical anesthesia intravitreal bevacizumab (IVB) (0.625 mg/0.025 ml) was injected. In right eye of the patients, Stivant was injected and in the left eye Avastin was injected. Patients were followed the day after injection and weekly for 4 weeks and then biweekly till retinal vascularization became complete. Safety and efficacy of bevacizumab under each brand name in regression of disease activity (plus disease regression) and achieve complete retinal vascularization were evaluated. Results: Fifteen infants (nne female) with gestational age (GA) of 27.5 ± 2.2 weeks and birth weight (BW) of 1202.08 ± 386.79 grams were included. IVB was performed at mean post-conceptional birth age of 34.8 ± 2.9 weeks. Only one case needed laser indirect ophthalmoscopy in both eyes, two weeks after IVB. In other cases Stivant was non-inferior to Avastin in regression of plus disease, decrease in ridge height, and progress in retinal vascularization. Endophthalmitis or uveitis was not seen in each patient. Conclusion: Stivant® was shown to be non-inferior to .Avastin® in terms of efficacy with a comparable safety profile in the treatment of prethreshold type I ROP

کلمات کلیدی: