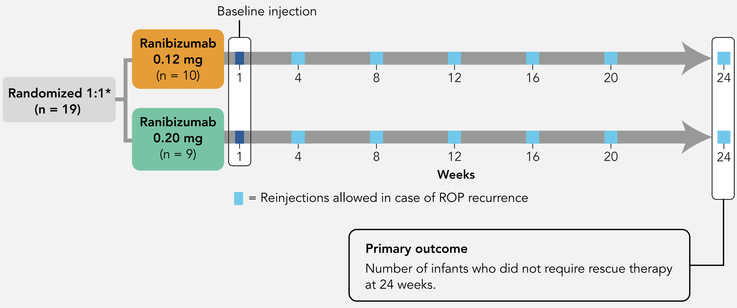
Comparing Alternative Ranibizumab Dosages for Safety and Efficacy in Retinopathy of Prematurity: A Randomized Clinical Trial

Stahl A, Krohne TU, Eter N, et al. *JAMA Pediatr.* 2018 1;172:278-286.
doi:10.1001/jamapediatrics.2017.4838

Anti-vascular endothelial growth factor (VEGF) therapies are a novel treatment option in retinopathy of prematurity (ROP). Data on dosing, efficacy, and safety are insufficient. This study aimed to investigate lower doses of anti-VEGF therapy with ranibizumab, a substance with a significantly shorter systemic half-life than the standard treatment, bevacizumab.

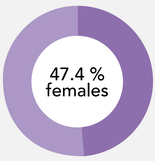
This study was a randomized, multicenter, double-blind, investigator-initiated trial across nine academic medical centers in Germany.



***Inclusion Criteria**

- Stage 1 ROP with plus disease
- Stage 2 ROP with plus disease
- Stage 3 ROP (with or without plus disease) in zone I of the studied eye
- Stage 3 ROP with plus disease in posterior zone II of the studied eye

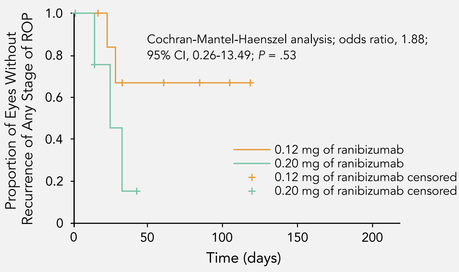
Gender of infants with ROP (n = 19)



Median postmenstrual age at first treatment

Both ranibizumab doses were equally effective in controlling acute ROP; systemic VEGF levels remained unchanged.

Time-to-event of recurrence of any ROP

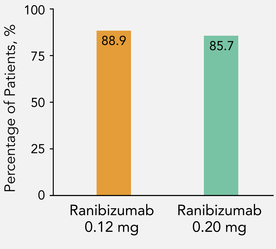


No. of patients at risk

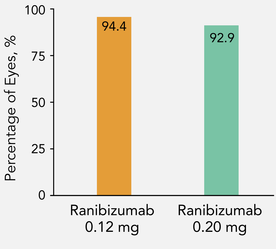
0.12 mg of ranibizumab	14	6	2	0	0
0.20 mg of ranibizumab	10	0	0	0	0

Of the surviving infants, 8 (88.9%) (17 eyes [94.4%]) in the 0.12 mg group and 6 (85.7%) (13 eyes [92.9%]) in the 0.20 mg group did not require rescue therapy.

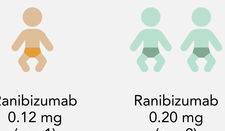
Surviving infants not requiring rescue therapy



Eyes not requiring rescue therapy



Number of deceased infants



Conclusions

This pilot study demonstrates that ranibizumab is effective in controlling acute ROP and that 24% of the standard adult dose (0.12 mg) appears equally effective as 40% (0.20 mg). Superior vascularization of the peripheral retina with 0.12 mg of ranibizumab indicates that the lower dose may be favorable.