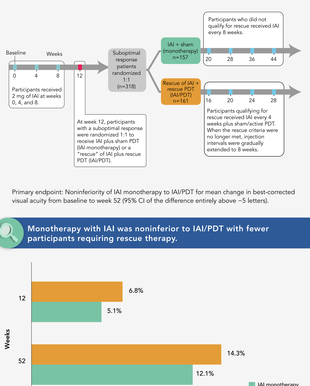
Efficacy and Safety of Intravitreal Aflibercept for Polypoidal Choroidal Vasculopathy in the PLANET Study: A Randomized Clinical Trial

Lee WK, Iida T, Ogura Y, et al. JAMA Ophthalmology. 2018;136:786-793.
doi:10.1001/jamaophthalmol.2018.1804

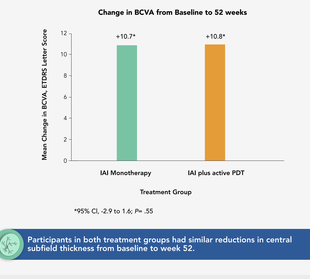
Polypoidal choroidal vasculopathy (PCV) is common in Asian populations, but an optimal treatment approach remains to be confirmed. The objective of this study was to evaluate intravitreal aflibercept injection (IAI) in participants with PCV and compare IAI monotherapy with IAI plus rescue photodynamic therapy (PDT).

This was a 96-week, double-masked, sham-controlled phase 3b/4 randomized clinical trial.



Primary endpoint: Noninferiority of IAI monotherapy to IAI/PDT for mean change in best-corrected visual acuity from baseline to week 52 (95% CI of the difference entirely above −5 letters).

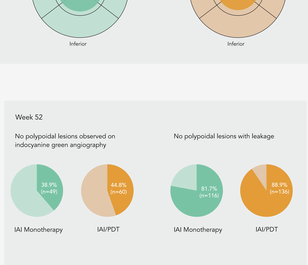
Monotherapy with IAI was noninferior to IAI/PDT with fewer participants requiring rescue therapy.



In this randomized clinical trial, of 318 older adults, 5.1% and 6.8% participants at 12 weeks (12.1% and 14.3% by 52 weeks) suboptimally responded to IAI alone or IAI plus active PDT, respectively. Monotherapy with IAI was noninferior to IAI plus PDT.

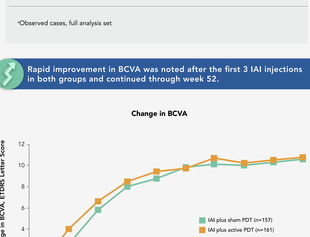
Monotherapy with IAI exhibited clinically meaningful Early Treatment Diabetic Retinopathy Study letter gains (+10.7); the benefits of adding PDT cannot be elucidated, as most participants responded to IAI alone.

Change in BCVA from Baseline to 52 weeks



*95% CI, -2.9 to 1.6; *P*= .55

Participants in both treatment groups had similar reductions in central subfield thickness from baseline to week 52.



Week 52

No polypoidal lesions observed on indocyanine green angiography

No polypoidal lesions with leakage

Additional Outcomes at Week 52

Characteristic	IAI Plus Sham PDT (n=157)	IAI Plus Active PDT (n=161)	*P* Value
Mean area of polypoidal lesions,* mm²			
Baseline	0.21	0.19	NA
Week 52	0.07	0.08	NA
Difference, baseline to week 52, %	-65.9	-60.9	NA

*Observed cases, full analysis set

Rapid improvement in BCVA was noted after the first 3 IAI injections in both groups and continued through week 52.

Change in BCVA

There was rapid and marked reduction in central subfield thickness (CST) after the first 3 IAI in both treatment groups that was maintained through week 52.

Change in CST

Over 52 weeks, the proportion of participants with an absence of fluid detected on OCT (investigator-assessed) increased in both groups.

OCT Results

There were two frequent ocular adverse events.

Conjunctival hemorrhage (IAI monotherapy, 8 [5.1%]).

Dry eye (IAI/PDT, 9 [5.6%]).

Conclusions and Relevance

Improvement in visual and/or functional outcomes was achieved in more than 85% of participants who were treated with IAI monotherapy, with no signs of leakage from polypoidal lesions in more than 80%. As fewer than 15% met the criteria of a suboptimal response to receive PDT, the potential benefit of adding PDT cannot be determined.